Magnesium

En

REF 08V5920

REF 08V5925

Alinity c

Diagnostic reagent for the determination of Magnesium concentration.
Liquid. Mono reagent. Store at +2/+8°C. For In Vitro Diagnostic use. **Do not freeze.**
The products with 08V5920/08V5925 reference numbers provided are compatible for use with Abbott Alinity biochemistry autoanalyzer series.

Changes made in the instructions for use are marked as gray.

The instructions must be followed carefully. The reliability of the test results cannot be guaranteed unless these instructions are followed.

NAME

Magnesium

INTENDED USE

The Magnesium (Mg) assay is used for the quantitative determination of Magnesium concentration in human blood, serum and urine on Alinity c analyzer.

SUMMARY AND EXPLANATION OF THE TEST

Magnesium is the fourth most abundant cation in the body and the second most common intracellular cation. The total body magnesium content is about 25 g (~1 mol), out of which about 55% is found in the skeleton. One-third of skeletal magnesium is thought to act as a reservoir to maintain extracellular magnesium concentration. About 45% of magnesium is intracellular. The concentration of magnesium in cells ranges from 2.4 to 7.3 mg/dL (1 to 3 mmol/L). In general, the higher the metabolic activity of a cell, the higher its magnesium content. In cells, most magnesium is bound to proteins and negatively charged molecules; 80 to 90% of cytosolic magnesium is bound to ATP, and MgATP is the substrate for numerous enzymes. The nucleus, mitochondria and endoplasmic reticulum contain significant amounts of magnesium. Approximately 0.5 to 5% of total cellular magnesium is free. The transport of magnesium across the cell membrane is regulated by a specific magnesium transport system. Extracellular magnesium accounts for about 1% of the total body magnesium content. In plasma, about 55% of magnesium is free, 30% is associated with proteins (mainly albumin) and 15% is complexed with phosphate, citrate and other anions.[1] Magnesium is a cofactor of more than 300 enzymes in the body.[2] It is required for the formation of substrates of enzymes (e.g. MgATP is a substrate for many enzymes that require ATP). Magnesium is also an allosteric activator of many enzyme systems. Enzymes that require magnesium for their activity include adenylate cyclase, Na+, K+-adenosine triphosphatase (ATPase), ALP, Ca^{+2}-ATPase, phosphofructokinase and creatine kinase. The guanine nucleotide containing the regulatory proteins Gs and Gi requires magnesium for its activity.

Magnesium is important in oxidative phosphorylation, glycolysis, cell replication, nucleotide metabolism and protein biosynthesis. A decrease in plasma magnesium concentration lowers the threshold for axonal stimulation and increases nerve conduction velocity. Magnesium also affects neurotransmitter release at neuromuscular junctions by competitively inhibiting the entry of calcium into presynaptic nerve terminals. Decreased plasma magnesium concentration results in increased neuromuscular excitability. Magnesium deficiency can therefore cause various metabolic abnormalities and clinical consequences.[1]

Daily magnesium intakes of 400 to 420 and 310 to 320 mg/day are recommended for adult men and women, respectively.[3] Between 20 and 80% of dietary magnesium is absorbed through the small intestine and absorption is proportional to the amount present in the diet. The kidneys play an important role in regulating magnesium balance. 70 to 80% of magnesium is ultra-filterable, where 15 to 25% is then passively reabsorbed in the proximal tubules. Then 65 to 75% is reabsorbed paracellularly with facilitated transport by the tight junction protein claudin-16 (also known as paracellin-1) and claudin-19 through the thick ascending arm of the henle handle. Between 5 and 10% of the filtered magnesium is reabsorbed intercellularly via the transient receptor potential melastatin 6 (TMRP6) in the distal convoluted tubules. Magnesium serves as an activator in various physiochemical processes, including phosphorylation, protein synthesis and DNA metabolism. It is also involved in neuromuscular transmission and in the excitability of skeletal and cardiac muscles.[1]

It has been reported that 10 percent of patients applying to hospitals and 65 percent of patients in intensive care units are hypomagnesemic.[4-7]

Moderate or severe magnesium deficiency is usually due to magnesium loss from the gastrointestinal tract or kidneys. Vomiting and nasogastric suction can deplete magnesium stores in the body, as upper gastrointestinal fluids contain about 1.2 mg/dL (<0.5 mmol/L) magnesium. More commonly, magnesium deficiency is associated with losses in the lower intestine. Diarrhea can cause significant magnesium losses; therefore, acute diarrheal conditions, regional enteritis and ulcerative colitis are often complicated by magnesium deficiency. Excessive urinary magnesium loss from the kidneys is an important cause of magnesium deficiency. Clinically important causes include alcohol, diabetes (osmotic diuresis), and the use of convulsive diuretics (e.g. furosemide), aminoglycoside antibiotics and proton pump inhibitors (e.g. omeprazole, lansoprazole). Increased sodium excretion (parenteral fluid therapy) and increased calcium excretion (hypercalcemic states) also cause renal magnesium loss. Familial hypomagnesemia has been reported in patients with loss-of-function mutations in TRPM6 and missense mutations in claudin genes. Since magnesium deficiency is often secondary to another disease process or a therapeutic agent, features of the primary disease process may complicate or mask magnesium deficiency. Neuromuscular overstimulation with tetany and seizures may be present. These signs and symptoms may also be due to hypocalcemia, and magnesium deficiency is a common cause of hypocalcemia.[1] Hypomagnesemia impairs PTH secretion and causes resistance to PTH in the kidneys and bone; it has been associated with osteoporosis in epidemiologic studies and animal experiments.[1,8]

One of the most serious complications of magnesium deficiency is cardiac arrhythmia. Premature atrial complexes, atrial tachycardia and fibrillation, premature ventricular complexes, ventricular tachycardia, torsades de pointes and ventricular fibrillation may occur in magnesium deficiency. These effects may be caused in part by hypokalemia, renal loss and intracellular potassium depletion caused by hypomagnesemia. Hypomagnesemia is often temporary and is not an indication of magnesium deficiency. Conversely, intracellular magnesium depletion and magnesium deficiency may be present despite a normal plasma magnesium concentration. Consequently, hypocalcemia, hypokalemia, neuromuscular hyperirritability and cardiac arrhythmias should be a warning against the possible presence of magnesium deficiency.

Although up to 12% of hospitalized patients may have a mild to moderate increase in serum magnesium concentration, magnesium intoxication is not a common clinical problem.[9,10] Symptomatic hypermagnesemia is almost always caused by excessive intake from administration of antacids, enemas and parenteral fluids containing magnesium. Many of these patients have coexisting renal insufficiency, which limits the ability of the kidneys to excrete excess magnesium. Magnesium used to treat pre-eclampsia and eclampsia can cause magnesium intoxication in mothers and newborns. Depression of the neuromuscular system is the most common manifestation of magnesium intoxication. Hypermagnesemia causes a decrease in plasma calcium concentration, probably due to inhibition of both PTH secretion and the end-organ action of PTH by magnesium. The possibility of magnesium intoxication should be considered, especially in patients with renal impairment who are taking magnesium. Replacement therapy should be ceased in patients with a mild to moderate increase in serum magnesium.[1]

PRINCIPLES OF THE PROCEDURE

The test has colorimetric measurement method. Xylidyl blue (1 – azo – 2 – hydroxy – 3 - [2,4 – di - methylcarboxanilido] naphthalene – 19 - [2 - hydroxybenzene]) binds magnesium in alkaline solution, causing a spectral shift and forming a red complex. The absorbance value measured at 546 nm is directly proportional to the Mg concentration in the sample.

REAGENTS

Kit Contents

R1 Xylidyl blue (≤ 0.12 mmol). NaCl (≤ 0.90 mol). EGTA (≤ 0.26 mmol). Triethanolamine (≤ 0.8 mmol). Good's buffer. Surfactant. Sodium azide (<0,1%). Preservative.

Ethylene glycol bis(2-aminoethyl ether)-N,N,N',N'-tetraacetic acid (EGTA), a calcium chelating agent, is added to reduce calcium interference. The reagents also contain surfactants to reduce interactions caused by proteins and lipids.

Warnings and Precautions

IVD: For in Vitro Diagnostic use only.
Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.
Contains sodium azide.

Danger
EUH032 : Releases a very toxic gas if contacts with acid.
H317 : May cause allergic skin reaction.

Precaution
P280 :Use protective gloves / clothes / glasses / mask.
P264 :Wash your hands properly after using.
P272 :Contaminated work clothes should not be allowed to be used outside of the workplace.

Intervention
P302+P352 :Wash with plenty of water and soap if it contacts with skin.
P333+P313 :Seek medical help if it irritates your skin or develops rash.
P362+P364 :Remove contaminated clothes and wash properly before using.

Disposal
P501 :Dispose the vials and contents according to the local regulations.

Reagent Handling

- Reagent cartridges should be kept in an upright position for at least 8 hours after receipt and before use to eliminate any air bubbles that may have formed inside.
- If the cartridge is dropped, it should be kept upright for 8 hours before use to allow the air bubbles to dissipate.
- Foam and air bubbles may form in the reagents; this may prevent accurate detection of the reagent level inside the cartridge, leading to insufficient reagent aspiration and potentially affecting the analysis results.

Reagent Storage [9]

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	+2/+8°C	Until expiration date	Store in upright position.
Onboard	System Temperature	21 days	

Indications of Reagent Deterioration

When a calibration error occurs or the control value falls outside the accepted range, the reagents may be considered to have deteriorated. In this case, the test results are not valid and the samples should be reanalyzed. Recalibration may be required.

Alternative Result Units

Use the unit conversion table provided below for alternative result units.

Default Unit	Conversion Factor	Result Unit
mg/dL	0.411	mmol/L
mmol/L	2.43	mg/dL
mEg/L	0.5	mmol/L
mEg/L	1.22	mg/dL

SAMPLE COLLECTION AND PREPARATION FOR ANALYSIS

Sample Types

The recommended sample types for this test are listed below.

Sample Type	Collection Tube
Serum	Serum tubes
Plasma	Li-Heparin
Urine	Metal-free urine containers

Follow the instructions provided with your sample collection tubes for use and handling.

Sample Conditions

- To obtain reliable results, serum should be free of fibrin, blood cells, or foreign particles. In samples obtained from individuals receiving anticoagulant or thrombolytic therapy, fibrin residues may be observed due to incomplete clotting.
- To reduce the risk of contamination between samples, a new pipette or pipette tip should be used for each procedure.
- Non-hemolytic samples should be used. Since erythrocytes contain higher concentrations of magnesium than serum or plasma, hemolyzed samples are not acceptable.
- Other anticoagulants, such as citrate, oxalate, and EDTA, should not be used because they form complexes with magnesium.
- Samples from patients undergoing EDTA therapy should not be used.
- Urine samples should be acidified until the pH reaches <2, and then stored.
- As in the cases of free calcium, high heparin concentrations should also be avoided. Certain silicones or other tube additives, as well as thiocyanate (found in smokers and those on diets), can interfere with free magnesium determinations.[1]
- To prevent magnesium precipitation, samples should be collected in containers containing boric acid or 6N HCl.[27] No more than 2.5 mL of 6N HCl should be used per 100 mL of urine; using more than this amount may result in elevated results. The concentration of boric acid should not exceed 10 g/L.

Preparation for Analysis

- When preparing sample tubes, the manufacturer's instructions should be followed; separation by standing alone is not sufficient.
- Samples should be free of air bubbles. Before analysis, bubbles should be removed using a stick, and a separate stick should be used for each sample.
- If the samples contain fibrin, red blood cells, or other particulate matter, centrifuge them again before testing to ensure reliable results.
- If samples do not appear homogeneous, they should be mixed by low-speed vortexing or by inverting the tube 10 times.
- The sample should be placed in a centrifuge tube and centrifuged; particularly in samples containing a lipid layer, the lipid-containing portion should not be transferred, and only the supernatant should be transferred to a separate container or secondary tube for testing.
- To prevent the precipitation of magnesium ammonium phosphate in urine samples, they should be acidified to pH 1 with concentrated HCl.[23]
- To prevent an increase in serum or plasma magnesium levels due to cell leakage, serum or plasma must be separated from the clot or red blood cells as soon as possible.
- Factors that alter the concentration of free calcium by changing the distribution of calcium between the free protein-bound and complex pools can also alter the concentration of free magnesium. For this reason, samples must be processed anaerobically to prevent carbon dioxide loss and analyzed without delay to prevent pH changes caused by metabolism.

Sample Storage

Temperature	Maximum Storage Time
+2/+8°C	3 days
+20/+25°C	8 hours
-20°C	3 months

The information provided applies to serum and plasma samples.[24] Repeated freeze–thaw cycles of samples should be avoided.

Temperature	Maximum Storage Time
+2/+8°C	3 days
+20/+25°C	3 days
-20°C	1 year

The information provided applies to urine samples.[25] Repeated freeze–thaw cycles of samples should be avoided.

PROCEDURE

Materials Provided
Magnesium Reagent Kit
Materials Required but Not Provided

- Multiconstituent Calibrator (Lyophilized) or commercially available controls
- Saline solution (0.85%–0.90% NaCl) for sample dilution

Assay Procedure

- If primary or aliquot tubes are used, ensure that a sufficient amount of sample is available.
- To prevent evaporation of the specimen, make sure that the tube volume is adequate before each test.
- Minimum Sample Volume Requirements:
  - Sample volume for a single test: 1,6 µL (serum/plasma),
  - This volume does not include dead space or the additional aspiration volume.

Sample Dilution Procedures

This method demonstrates measurement linearity up to 5.0 mg/dL. For samples with results above this value, the automatic dilution procedure of the autoanalyzer should be applied or manual dilution may be performed.

Automatic Dilution Protocol

The system dilutes serum and plasma samples and automatically calculates the concentration by multiplying the result by the dilution factor. The dilution ratio for serum is 1:10.

Manual Dilution Procedures

Dilute the sample with a 0.85%–0.90% NaCl solution in a 1:2 ratio. Enter the dilution factor on the relevant screen of the device. If the user does not enter the dilution factor, the result must be manually multiplied by the correct factor before it is reported. If the result of the diluted sample is below the lower limit of the measurement range, the result is not reported, and the procedure is repeated with an appropriate dilution.

Calibration

The use of a Lyophilized Multiconstituent Calibrator is required for this test.

Multiconstituent Calibrator (Lyophilized)
Ref.No: 06R56-02

Calibration stability is 3 days. Changes in the reagent lot number require recalibration. Calibration is necessary if quality control results are not within acceptable limits.

Quality Control Procedures

Commercially available control materials with values assigned by this method may be used.

At least two levels of control should be run every 24 hours. Each laboratory should establish its own quality control procedures. If more stringent control monitoring is required, refer to the quality control procedures established for your laboratory.

EXPECTED VALUES

Each laboratory should investigate the transferability of expected values for its own patient population and, if necessary, establish its own reference range.

Reference Range [13.26]

Serum/Plasma

Newborn	: 1.5 – 2.2 mg/dL
5 month-old - 6 year-old	: 1.7 – 2.3 mg/dL
6 - 12 year-old	: 1.7 – 2.1 mg/dL
12 - 20 year-old	: 1.7 – 2.2 mg/dL
Adult	: 1.6 – 2.6 mg/dL

Urine

24 hour	: 72,9 – 121,5 mg/day

To convert results from mg/dL to mg/day for 24-hour urine excretion:

24 hour urine = [(V x c) / 100] mg/day

V = 24-hour urine volume (mL)
c = analyte concentration (mg/dL)

There are several important clinical decision thresholds related to serum/plasma magnesium concentrations:

- 1 mg/dL (0,41 mmol/L): This is the concentration at which clinical magnesium deficiency is observed.
- Deep tendon reflexes disappear at plasma magnesium concentrations above 5 to 9 mg/dL (2.06 to 3.7 mmol/L), while at concentrations above 10 to 12 mg/dL (4.11 to 4.94 mmol/L), respiratory depression and apnea caused by voluntary muscle paralysis may occur.
- Higher concentrations may cause cardiac arrest. Drowsiness, hypotension, nausea, vomiting, and skin flushing may also occur.
- Magnesium levels may be higher in women who are menstruating.

Since reference concentrations at the lower end may be associated with cardiovascular risk, the appropriate reference range is, to certain extent, a matter of debate.[12]

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

			Within-Run (Repeatability)[17,18]		Within-Laboratory (Total)*[17,18]	
Sample	n	Mean (mg/dL)	SD	%CV	SD	%CV
Level 1	80	1.97	0.03	1.52	0.08	4.06
Level 2	80	3.34	0.07	2.09	0.11	3.29

*: Includes within-run, between-run, and between-day variability.

Lower Measurement Limits

The lower measurement limits refer to the range between the lower limit of quantitation (LLoQ) and the upper limit of quantitation (ULoQ), within which the analyte concentration can be measured with the required medical and laboratory accuracy without dilution, concentration, or any pre-treatment.[14] The LoD and LoQ values have been verified using the CLSI EP17-A2:2012 protocol.[15]

	mg/dL
LoD**	0.27
LoQ***	0.51

**** :** The LoD represents the lowest concentration at which the analyte can be detected with 95% probability, based on ≥ 60 replicates of samples with low analyte levels.
*****:** When determining the LoQ value, a coefficient of variation (%CV) of ≤20% is used as the basis.

Measuring Interval

This method shows measurement linearity in the activities between 0.51-5.0 mg/dL. For samples with results above this value, the automatic dilution procedure should be applied. For additional information, please refer to the instrument's user manual. Linearity studies data have been verified by using CLSI EP06-A:2003 protocol.[16]

Interference

Endogenous interferant and analyte concentrations that have been used in the Magnesium scanning tests has been determined according to "CLSI EP37-ED1:2018" and "CLSI EP07-ED3:2018" manuals.[20,21]

The total acceptable error rate, which is going to be used to detect whether the observed differential value obtained from Magnesium interference scanning test is appropriate, is determined as ±10%.[22]

In Magnesium test results, no significant interaction has been observed in the determined endogenous interferant and analyte concentrations or between interferants and analyte.

Interferant-Concentration	Mg Target (mg/dL)	N*	Observed Recovery %
Bilirubin 7.11 mg/dL	1.62	3	110
Lipemia 433 mg/dL	1.89	3	106

*In calculating how many times the control and test samples (containing interferent), prepared as a serum pool, would be run repetitively, the within-run SD values previously determined for the relevant method and the total allowable error rate defined as the interference limit were used. In the calculations, a type 1 error (α error) rate of 5% and a type 2 error (β error) rate of 10% (90% power) were accepted.[21]

Interference caused by icterus or lipemia depends on the method and can be reduced by performing bichromatic analysis and blind reading. Lipemic samples must be ultracentrifuged.[1]

It should be noted that, in addition to endogenous interferents, various drugs and metabolites; anticoagulants (e.g., heparin, EDTA, citrate, oxalate) and preservatives (e.g., sodium fluoride, iodoacetate, hydrochloric acid); substances that may come into contact with samples during collection and handling (such as serum separation devices, sample collection containers and their contents, catheters, catheter flushing solutions, skin disinfectants, hand sanitizers and lotions, glassware detergents, powdered gloves, etc.); dietary substances known to affect certain tests (e.g., caffeine, beta-carotene, poppy seeds); or certain substances present in a sample that may cause interference due to foreign proteins (e.g., heterophilic antibodies), autoimmune responses (e.g., autoantibodies), or malignancy (e.g., paraproteins causing interference in phosphate tests and indirect ion-selective electrode methods) may lead to various interferences and erroneous evaluations for many different reasons.[21]

These performance characteristics were obtained using an autoanalyzer. Results may vary when different equipment or manual procedures are used.

Method Comparison

As a result of the statistical evaluation of method comparison data, the table was constructed according to the Passing–Bablok regression method as follows :[19]

Archem Mg – Roche Cobas Integra 400 Plus

Units		n	Correlation Coefficient	Intercept	Slpoe	Concentration Range
Serum	mg /dL	100	0.9995	0.056	0.95	0,65-4,95

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SYMBOLS

IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
R1	Reagent 1
GTIN	Global Trade Item Number
REF	Reference Number
GLP	Good Laboratory Practice
FOR USE WITH	Identifies Products to Be Used Together
PRODUCT OF TURKEY	Product of Turkey
	Manufacturer
	Expiration Date
	Temperature Limits
	Consult Instructions for Use
	Caution
	Number of Tests