Infinity™ Magnesium Arsenazo Liquid Stable Reagent

PRODUCT SUMMARY

Stability	:	Until expiry at 2-25°C
Linear Range	:	0.0-2.0 mmol/L (0.00-4.86 mg/dL)
Specimen Type	:	Serum, plasma or urine
Method	:	Endpoint
Reagent Preparation	:	Supplied ready to use.

IVD

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorized Representative		Temperature Limitation
IVD	For in vitro diagnostic use		Use by/Expiration Date
LOT	Batch code/Lot number		CAUTION. CONSULT INSTRUCTIONS FOR USE.
REF	Catalogue number		Manufactured by
	Consult instructions for use		Xn - Harmful

INTENDED USE
This reagent is intended for the in vitro quantitative determination of magnesium in 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 21-28 gram of 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.
Hypomagnesaemia results in the impairment of neuromuscular function and may develop in severe prolonged diarrhoea, malabsorption syndromes, primary aldosteronism and diuretic therapy. Hypermagnesaemia is seen in renal glomerular failure and diabetic coma[1,2].

METHODOLOGY
The preferred method for the determination of Magnesium is by Atomic Absorption Spectrophotometry however, as this technique is not available to all laboratories, a number of simple and rapid colourimetric methods have been developed. The commonly used methods employ dyes such as Xylidyl Blue (Magon) and Calmagite. Poor calibration stability, the need to use cyanide to prevent heavy metal contamination and limited stability of working reagents are just some of the problems with the more common colourimetric methods.
The Infinity Arsenazo Magnesium reagent is a unique formulation for the measurement of magnesium in serum, plasma and urine. The reagent utilises an Arsenazo dye which binds preferentially with magnesium. The absorbance of the Arsenazo Magnesium complex is measured at 570 nm and is proportional to the concentration of magnesium present in the sample. Calcium interference is prevented by incorporation of an unconventional calcium chelating agent.

Arsenazo Dye $\xrightarrow{Mg^{2+}}$ Mg-Arsenazo Dye Complex

REAGENT COMPOSITION

Active Ingredient	Concentration
Tris Buffer	100 mmol/L
Arsenazo Dye	0.13 mmol/L
Chelating Agent	0.20 mmol/L

Reagent also contains surfactants and stabilizers necessary for optimum reagent performance.
pH 8.8 ± 0.1 at 20°C

WARNING: Do not ingest. Avoid contact with skin and eyes. If spilt thoroughly wash affected areas with water. Reagent contains sodium azide which may react with copper and lead plumbing. Flush with plenty of water when disposing. For further information consult the Infinity Magnesium Arsenazo Reagent Material Safety Data Sheet.
R22 Harmful if swallowed
S28 After contact with skin, wash immediately with plenty of soap and water.

REAGENT PREPARATION
Reagent is supplied ready to use.

STABILITY AND STORAGE
When stored between 2-25°C the reagent is stable until the expiry date stated on the bottle and kit box label. Reagent is light sensitive, avoid excessive exposure to light.
Indications of Reagent Deterioration:
- Turbidity;
- Reagent Absorbance >0.7 AU at 570 nm (1cm); and/or
- Failure to recover control values within the assigned range.

SPECIMEN COLLECTION AND HANDLING [3,4]
Serum: Use non-haemolysed serum separated from the cells as soon as possible following collection.
Plasma: Use heparin. Do not use EDTA, Oxalate or Citrate.
Urine: Accurate analysis of urine magnesium can only be performed if all precipitated magnesium is dissolved prior to testing. Twenty four hour urine specimens should be acidified with 15 mL concentrated HCl. Non acidified specimens which have been refrigerated should be acidified and/or heated at 60°C to redissolve any precipitate. Acidified specimens are not suitable for urate or creatinine estimations. Urine samples should be diluted 1 in 2 with an equal volume of deionised water before analysis.
Storage: Magnesium in serum or plasma is stable for 1 week at room temperature (18-25°C). For longer storage the sample should be tightly capped and stored frozen (-20°C).[3] Urine specimens are stable for 1 week when stored at 4°C.[4]

ADDITIONAL EQUIPMENT REQUIRED BUT NOT PROVIDED
- A clinical chemistry analyser capable of maintaining constant temperature (37°C) and measuring absorbance at 570 nm (550-590 nm).
- Analyser specific consumables, eg: sample cups.
- Normal and abnormal assayed control material.
- Calibrator or a suitable aqueous Magnesium standard.

ASSAY PROCEDURE
The following system parameters are recommended. Individual instrument applications are available upon request from the Technical Support Group.

SYSTEM PARAMETERS

Temperature	37°C
Primary Wavelength	570 nm (550 - 590nm)
Secondary Wavelength	700 nm (650 - 800nm)
Assay Type	Endpoint
Direction	Increase
Sample : Reagent Ratio	1 : 60
eg: Sample Vol	5 µL
Reagent Vol	300 µL
Incubation Time	60 Seconds
Reagent Blank Limits	Low 0.3 AU
(570nm, 1cm lightpath)	High 0.7 AU
Linearity	0.0-2.0 mmol/L (0.00-4.86 mg/dL)
Sensitivity (570nm, 1cm lightpath)	0.169 ΔA per mmol/L (0.068 ΔA per mg/dL)

CALCULATIONS
Results are calculated usually automatically by the instrument, as follows:

$$\text{Magnesium} = \frac{\text{Absorbance of Unknown}}{\text{Absorbance of Calibrator}} \times \text{Calibrator Value}$$

Example:
Absorbance of calibrator = 0.12
Absorbance of unknown = 0.06
Value of calibrator = 1.00 mmol/L (2.43 mg/dL)

$$\text{Magnesium} = \frac{0.06}{0.12} \times 1.00 = 0.50 \text{ mmol/L}$$

$$\text{Magnesium} = \frac{0.06}{0.12} \times 2.43 = 1.22 \text{ mg/dL}$$

To convert urine results from mmol/L to mmol/24 Hours, the following formula should be used:

Urine Magnesium (mmol/24 hours) = Mg Result (mmol/L) x Dilution Factor x Volume (L)

Example:
Mg Result = 0.81 mmol/L
Dilution = 1 : 2
24 Hour Vol = 1.25 litres
Urine Mg = 0.81 x 2 x 1.25 = 2.03 mmol/24 Hrs

Thermo SCIENTIFIC

NOTES

1. The reagent and sample volumes may be altered proportionally to accommodate different spectrophotometer requirements.
2. The temperature of the reaction is not critical, however the temperature of the spectrophotometer should be held constant.
3. The colour developed is stable for one hour.
4. Unit Conversion: mmol/L x 2.43 = mg/dL
   mmol/L x 2 = mEq/L

CALIBRATION

Calibration is required. An aqueous standard or serum based calibrator, with and assigned value traceable to a primary standard (eg NIST or IRMM) is recommended. For calibration frequency on automated instruments refer to the instrument manufacturers specifications. However, calibration stability is contingent upon optimum instrument performance and the use of reagents which have been stored as recommended in the stability and storage section of this package insert. Recalibration is recommended at anytime if one of the following events occurs:-

- The lot number of reagent changes.
- After preventative maintenance is performed or a critical component is replaced.
- Control values have shifted or are out of range and a new vial of control does not rectify the problem.

QUALITY CONTROL

To ensure adequate quality control, normal and abnormal controls should be run as unknown samples:-

- At least every eight hours.
- When a new bottle of reagent is used.
- After preventative maintenance is performed or a critical component is replaced.

Control results falling outside the upper or lower limits of the established ranges indicate the assay may be out of control.

The following corrective actions are recommended in such situations:-

- Repeat the same controls.
- If repeated control results are outside the limits, prepare fresh control serum and repeat the test.
- If results are still out of control, recalibrate with fresh calibrator, then repeat the test.
- If results are still out of control, perform a calibration with freshly prepared reagent, then repeat the test.
- If results are still out of control, contact Technical Services or your local distributor.

LIMITATIONS

1. Care must be taken to avoid magnesium contamination. The use of disposable plastic tubes or cuvettes is strongly recommended. The user should assure themself that such disposables are free from magnesium contamination. If glassware is used, it should be soaked in dilute HCl or a strong laboratory cleanser and thoroughly rinsed with distilled or deionised water.
2. Haemolysis will produce falsely elevated results because of the high concentration of intracellular magnesium.
3. Calcium if present at a concentration >5.0 mmol/L, will interfere with this method.
4. Studies to determine the level of interference from bilirubin (free & conjugated) and lipaemia were carried out using commercially available interference check products. The following results were obtained:
   Free bilirubin: No interference from free bilirubin up to a level of 265 µmol/L (15.5 mg/dL).
   Conjugated bilirubin: No interference from conjugated bilirubin up to a level of 286 µmol/L (16.7 mg/dL).
   Lipaemia: No interference from lipaemia, measured as triglycerides, was observed up to a level of 3.1 mmol/L (270 mg/dL).
5. For a more comprehensive review of factors affecting magnesium assays refer to the publication by Young[5].

EXPECTED VALUES

Serum/Plasma:	0.66 - 1.07 mmol/L	(1.6-2.6 mg/dL) [2]
Urine:	1.0-10.5 mmol/24 Hrs	(24-255 mg/24 Hrs) [4]

The quoted values are representative of the expected range for this method and should serve as a guide only. It is recommended that each laboratory verify this range or derive a reference interval for the population it serves.[6]

PERFORMANCE DATA

The following data was obtained using the Infinity Magnesium Arsenazo Reagent on a well maintained automated clinical chemistry analyser. Users should establish product performance on their specific analyser used.

IMPRECISION

Imprecision was evaluated using two levels of commercial control.

Within Run:	Serum:		Urine:	
	Level I	Level II	Level I	Level II
Number of data points	20	20	20	20
Mean (mmol/L)	0.93	1.71	0.55	1.30
Mean (mg/dL)	2.26	4.16	1.34	3.16
SD (mmol/L)	0.01	0.02	0.01	0.02
SD (mg/dL)	0.02	0.05	0.02	0.05
C.V. (%)	1.08	1.17	1.82	1.54

Between Run:	Serum:		Urine:	
	Level I	Level II	Level I	Level II
Number of data points	20	20	25	25
Mean (mmol/L)	0.98	1.78	0.55	1.30
Mean (mg/dL)	2.38	4.33	1.34	3.16
SD (mmol/L)	0.02	0.03	0.01	0.02
SD (mg/dL)	0.05	0.07	0.02	0.05
C.V. (%)	2.04	1.69	1.82	1.54

ACCURACY

The Arsenazo Magnesium was first validated using the preferred method for Magnesium determination, Atomic Absorption Spectrophotometry (AAS). Normal and abnormal human plasma and serum samples were assayed and the results compared by least squares regression. The following statistics were obtained:

Number of sample pairs	21
Range of sample results	0.2 - 2.0 mmol/L (0.49 - 4.86 mg/dL)
Slope	0.90
Intercept	0.16 mmol/L (0.39 mg/dL)
Correlation Coefficient	0.99

Comparison studies were also carried out using commercially available colourimetric Magnesium reagent. Normal and abnormal human serum, plasma and urine samples were assayed in parallel and the results compared by least squares regression. The following statistics were obtained:

Serum/Plasma:	
Number of sample pairs	56
Range of sample results	0.13 - 1.45 mmol/L (0.32 - 3.52 mg/dL)
Mean of reference method results	0.83 mmol/L (2.02 mg/dL)
Mean of Magnesium results	0.87 mmol/L (2.11 mg/dL)
Slope	1.02
Intercept	0.01 mmol/L (0.02 mg/dL)
Correlation Coefficient	0.99

Urine:	
Number of sample pairs	37
Range of sample results	0.12 - 4.12 mmol/L (0.29 - 10.01 mg/dL)
Mean of reference method results	1.32 mmol/L (3.21 mg/dL)
Mean of Magnesium results	1.25 mmol/L (3.04 mg/dL)
Slope	0.95
Intercept	0.005 mmol/L (0.01 mg/dL)
Correlation Coefficient	0.997

LINEARITY

When run as recommended the assay is linear to 2.0 mmol/L (4.86 mg/dL)

SENSITIVITY

When run as recommended the sensitivity of this assay is 0.169 ΔAbs per mmol/L or 0.068 ΔAbs per mg/dL (1cm light path, 570 nm).

REFERENCES

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4. Farrell EC “Magnesium” in Clinical Chemistry. Theory, Analysis and Correlation. The CV Mosby Company. Kaplan LA, Pesce AJ (Ed) 1984;Chapter 55:1065-70.
5. Young DS. Effects of Drugs on Clinical Laboratory Tests. Third Edition 1990; 3:237-9.
6. Wachtel M et al, Creation and Verification of Reference Intervals. Laboratory Medicine 1995; 26:593-7.

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REF

Reorder Information

Catalogue No.	**Configuration**
TR31126	2 x 250 mL