ACCUCARE®

MAGNESIUM

Xylidyl Blue

Quantitative determination of Magnesium in serum / Plasma / CSF / Urine
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Cont.
MAG 25	25 X 1 mL
MAG 100	2 X 50 mL

CLINICAL SIGNIFICANCE

Magnesium is the second most abundant intracellular cation of the human body after potassium, being essential in great number of enzymatic and metabolic processes. Is a cofactor of all the enzymatic reactions that involve the ATP and comprises of the membrane that maintains the electrical excitability of the muscular and nervous cells. A low magnesium level is found in malabsorption syndrome, diuretic or aminoglucoside therapy; hyperparathyroidism or diabetic acidosis. Elevated concentration of magnesium is found in uremia, chronic renal failure, glomerulonephritis, Addisons's disease or intensive anti acid therapy. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Method

Photometric test using xylidyl blue.

PRINCIPLE

At alkaline pH magnesium reacts with xylidyl blue and produces a chelating red colored compound. The red increasing color is proportional to magnesium concentration.

REAGENT

Reagent 1 : Magnesium Reagent
Magnesium Standard : 2.5 mg/dl (1.04 mmol/L)

REAGENT PREPARATION

The reagent is provided in a ready to use format.

REAGENT STORAGE AND STABILITY

The reagent included is stable, unopened or opened, at 15-30°C until the expiry date stated on the label.

WARNING AND PRECAUTIONS

- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

WASTE MANAGEMENT

Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED

- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION

Serum, plasma, cerebrospinal fluid (CSF) or urine
Do not use EDTA plasma.
Stability:
in serum/plasma: 7 days at 4 – 8°C
1 year at –20°C
in urine: 3 days at 4 – 8°C
1 year at –20°C
Acidify urine with some drops of conc. HCl to pH 3-4, then dilute 1+4 with dist. water; multiply the result by 5.

Freeze only once! Discard contaminated specimens!

ASSAY PROCEDURE

Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 – 28 ºC, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	505 nm (490-550 nm)
Reaction Type	End Point
Cuvette	1 cm light path
Reaction Temperature	Room temperature
Reaction Type	Increasing
Measurement	Against Reagent Blank
Sample Volume	10µl
Reagent Volume	1000µl
Incubation	05 minutes
Low Normal	1.6 mg/dL(0.65 mmol/L)
High Normal	2.6 mg/dl (1.05 mmol/L)
Linearity	5.0mg/dL (2.08 mmol/L)

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

	BLANK	STD	SAMPLE
Sample	-	-	10µl
Standard	-	10µl	-
Reagent	1000µl	1000µl	1000µl

Mix & Incubate for 05 min. at R.T. Measure absorbance of Sample (AT) and Standard (AS) against Reagent Blank at 505 nm. The colour is stable for 30 min. at R.T.

SAMPLE DILUTIONS

- This method is linear upto a concentration of 5.0 mg/dL.
- Dilute samples above this concentration 1:1 with 0.9% saline
- Repeat assay. Multiply the result by 2.

CALCULATION

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

Magnesium (mg/dl) = AT/AS x Conc. of Standard

CALIBRATORS AND CONTROLS

For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

The assigned values of the **Magnesium Standard** have been made traceable to the reference method Atomic Absorption Spectrometry (AAS).

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

Each laboratory should establish corrective action in case of deviations in control recovery.

PERFORMANCE CHARACTERISTICS

WITHIN RUN

Sample	Mean Concentration	SD	CV %
Norm	1.89	0.05	2.85%
Path	2.74	0.09	3.40%

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Effective Date: 20/09/2019
Revision No.: 01

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Norm	1.89	0.05	2.68%
Path	2.74	0.08	2.83

LINEARITY

The method is linear upto a concentration 5.0 mg/dl (2.08 mmol/L). Dilute samples above this concentration 1:1 with 0.9% saline solution and repeat assay. Multiply the result by 2.

Limit of detection: The limit of detection for Magnesium is 0.1 mg/dl.

METHOD COMPARISON

A comparison of Accucare Magnesium with a commercially available assay (x) using 59 samples gave following results: $R^2 = 0.991$

REFERENCE VALUES

SERUM / PLASMA	1.6 - 2.6 mg/dl (0.65 – 1.05 mol/L)
CSF	2.4 - 3.1 mg/dl (1.9 - 2.5 mEq/l)
URINE	24 - 244 mg/24h (2 - 21 mEq/L/24 hr)

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

INTERFERENCE

- Hemoglobin: No interference found upto 500 mg/dL.
- Bilirubin: No interference found upto 43mg /dL.
- Lipemia: No interference found upto 1100 mg/dL.
- Calcium: No interference found upto 33 mg/dL.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 231-41.
2. Endres DB, Rude RK. Mineral and bone metabolism. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1395–1457.
3. Guder WG, Zatwa B et al. The quality of Diagnostic Samples. 1st ed. Darmstadt: Git Verlag, 2001: 38-39, 50-51.

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer	IVD	For *in vitro* Diagnostic use only
	Keep away from sunlight	CONT	Content of the kit

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No.: 3225, Chemical Zone,
GIDC Sarigam – 396155, Dist. Valsad, Gujarat, India.
Tel.: +91 22 2554 2109 /1558
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