



MAGNESIUM LR liquid reagent

REF C4400620 518 Test

CE C4400620A 518 Test
IVD For in vitro medical device

Use

Kit for measurement of magnesium in serum, plasma and urine. Colorimetric method Xylidyl Blue

Summary

Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia which is associated with conditions such as tetany, malabsorption, chronic alcoholism, acute pancreatitis and of hypermagnesemia which is observed in dehydration, severe diabetic acidosis and Addison's disease.

Principle

End point analysis. Magnesium reacts, in alkaline environment, with Xylidyl Blue forming Mg-Xylidyl blue complex. The increase in absorbance is proportional to the magnesium concentration in the sample.

Reagents

R1	Goods buffer	175.0 mmol/l
	potassium carbonate	60.0 mmol/l
	EGTA	0.04 mmol/l
	Xylidyl Blue	0.12 mmol/l

Reagent Preparation

Reagents are liquid and ready to use.

Storage and stability

- Store the kit at 15-25°C.
- After opening, the R1 vial is stable 30 days if recapped immediately and protected from contamination, evaporation, direct light, and stored at the correct temperature.

Precaution in Use

The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998). However the reagent should be handled with caution, according to good laboratory practice. Caution: the reagents contain Sodium Azide (0.095%) as preservative. Avoid swallowing and contact with skin, eyes and mucous membranes.

Waste Management

Please refer to the local legal requirements.

Specimen Collection and Preparation

- Serum or plasma.
- Diluted urine 1:4.
- Do not use samples with haemolysis.
- Do not use EDTA as anticoagulant.
- The magnesium is stable in the samples up to 5 days at 2-8°C.

Note

- The kit, according to this method, must be used in manual procedures. About automatic using follow specific applications.
- Avoid direct light, contamination and evaporation.
- In case of complaint or quality control request, refer to the lot number on the package or the lot number on the single vials.

Procedure

Wavelength	λ: 520 (500-550) nm
Working Temperature	37°C
Optical path	1 cm
Reaction	"end point" (increasing)

-- Monoreagent Procedure "sample starter"

	BLANK	STD	SAMPLE
Working Reagent	2000 µl	2000 µl	2000 µl
Distilled Water	20 µl	--	--
Sample	--	--	20 µl
Standard	--	20 µl	--

Mix, then incubate for 5' at 37°C (15-25°C). Measure the absorbance of the sample (EC) and standard (ESTD) against the reagent blank.

Calculation

$$\text{Magnesium [mg/dl] o [mmol/l]} = \text{EC/ESTD} \times \text{Conc. STD}$$

The reagent performances are related to 37°C, 1 cm and 520 nm.

Conversion Factor

$$\text{Magnesium [mg/dl]} \times 0.41 = \text{Magnesium [mmol/l]}$$

Reference Values

Serum or plasma	1.7 – 2.1 mg/dl	1.2 – 2.3 mEq/l
Urine	75 – 125 mg /dl 24h	

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

ANALYTICAL PERFORMANCES

Linearity

Reaction is linear up to a concentration of 10 mg/dl. Samples with values exceeding 10 mg/dl must be diluted with saline solution. Then, multiply, the result for diluting factor.

"Intra-Assay" precision (within-Run)

Determined on 20 samples for each control (N-H) (Normal- High). Results:

MEAN (mg/dl)	N = 2.55	H = 4.37
S.D.	N = 0.12	H = 0.11
C.V.%	N = 4.89	H = 2.53

"Inter-Assay" precision (between-Run)

Determined on 20 samples for each control (N-H) (Normal- High). Results:

MEAN (mg/dl)	N = 2.49	H = 4.39
S.D.	N = 0.06	H = 0.10
C.V.%	N = 2.31	H = 2.38

Analytical sensitivity

The test sensitivity in terms of detection limit is: 0.08 mg/dl.

Correlation

A study based comparing this method with a similar method on 20 samples has given a correlating factor: $r = 0.9592$

$$y = 0.9546x + 0.1002$$

Interferences

No interference was observed by the presence of:
Bilirubin ≤ 25 mg/dl
Triglycerides ≤ 800 mg/dl
Hemoglobin ≤ 50 mg/dl
For a comprehensive review of interfering substances, refer to the publication by Young.

Quality controls

It's necessary, every time the kit is used, to make the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Bibliography

Kaplan, L.A., Pesce, A.J.: "Clinical Chemistry", Bohuon, C. Clin. Chem. Acta 16, 155 (1957). Mann, C.I. and Yoe, J.H., Anal. Chem. 28,202 (1955). Fragar, D.A., Casey, Clin. Biochem., 791 (1974). Young D.S., Effects of Drugs on Clinical Laboratory Tests, AACC Press, Washington, DC 5th ed.2000.

Symbols

CE CE Mark (requirement of 98/79 regulation)

IVD in vitro medical device

LOT Batch Code

Use by

Storage temperature limits
Read instruction for use

Gesam Production srl

Magnesium LR

MOD.7.3.5 Rev. 0 del 2006-03

Gesam Production s.r.l.

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