SBio MAGNESIUM KIT

(Calmagite Method)

(For invitro diagnostic use only)

REF	90590225
Pack Size	2 x 25 ml

CE

8°C / 2°C Store at 2-8°C	Manufacturer	IVD *In vitro* Diagnostic Medical Device	L2 Colour Reagent	Calmagite Calmagite Method
Use by (Last day of stated month)	Consult Instructions for use	LOT Batch Number	S Magnesium Standard (2.0 mEq/L)	EC REP Authorised Representative in the European Community
Date of Manufacture	REF Catalogue Number	L1 Buffer Reagent	This way up	

INTENDED USE

Magnesium Kit is used for the determination of Magnesium in serum, urine and CSF.

PRINCIPLE OF THE TEST

Magnesium combines with Calmagite in an alkaline medium to form a red coloured complex. Interference of calcium and proteins is eliminated by the addition of specific chelating agents and detergents. Intensity of the colour formed is directly proportional to the amount of magnesiurn present in the sample.

Magnesium + Calmagite —(Alkaline / Medium)→ **Red coloured complex**

CLINICAL SIGNIFICANCE

Magnesium, along with potassium, is a major intracellular cation. It is an activator of various enzymes. It is also involved in amino acid activation and protein synthesis. Increased levels are found in dehydration, Addison's disease and uremia. Decreased levels are found in malabsorption, during treatment of diabetic coma, chronic renal disease, chronic alcoholism, pancreatitis and hyperthyroidism.

PRESENTATION	**2 x 25 ml**
L1 : Buffer Reagent	25 ml
L2 : Colour Reagent	25 ml
S : Magnesium Standard (2.0 mEq/L)	5 ml

COMPOSITION

AMP Buffer 500 mM; pH 11.2; Calmagite 0.15 mM; EGTA 0.35 mM; Detergent.

STORAGE / STABILITY

Contents are stable at 2-8°C till the expiry mentioned on the labels.

SAMPLE REQUIRED

Serum (Free from hemolysis), Urine and CSF.
24-hr.collected urine should be acidified to a pH of 2-3 by the addition of approx. 10 to 15 ml conc. HCl and diluted 1+ 3 with D.Water before use. Multiply results by 4.

REAGENT PREPARATION

Reagents are ready to use. Protect from bright light.

Working reagent: For larger assay series a working reagent may be prepared by mixing equal volumes of L1 (Buffer Reagent) and L2 (Colour Reagent). The Working reagent is stable at 2-8°C for at least one month. Keep tightly closed.

SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.
This product requires the handling of human specimen. It is recommended that all human sourced material are considered potentially hazardous and are handled in accordance with the OSHA standard on blood borne pathogens.
Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.
Handle specimen, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

PROCEDURE

Wavelength / filter : 510 nm (Hg 546 nm)/Green
Temperature : R. T.
Light path : 1 cm

MATERIALS REQUIRED BUT NOT PROVIDED

General laboratory instrumentation like Spectrophotometer/Analyzer, Thermostatic Cuvette holder, Cuvettes, Micropipettes, Test tubes, Waterbath, Stopwatch/Timer.

Pipette into clean dry test tubes labeled as Blank (B), Standard (S), and Test (T):

Addition Sequence	B (ml)	S (ml)	T (ml)
Buffer Reagent (L1)	0.5	0.5	0.5
Colour Reagent (L2)	0.5	0.5	0.5
Distilled water	0.01	-	-
Magnesium Standard (S)	-	0.01	-
Sample	-	-	0.01

Mix well and incubate at R. T. (25°C) for 5 minutes. Measure the absorbance of the Standard (Abs. S), and Test Sample (Abs.T) against Blank, within 30 minutes.

CALCULATIONS

$$\text{Magnesium in mEq/L} = \frac{\text{Abs.T}}{\text{Abs.S}} \times 2$$

QUALITY CONTROL

The following process is recommended for QC during the assay of Magnesium. *Define and establish acceptable range for your laboratory.

1. Two levels of control (Normal and Abnormal) are to be run on a daily basis.
2. If QC results fall outside acceptance criteria, recalibration may be necessary.
3. Review QC results and run acceptance criteria following a change of reagent lot.

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity:
This procedure is linear upto 10 mEq/L. If values exceed this limit, dilute the sample with distilled water and repeat the assay. Calculate the value using an appropriate dilution factor.

Limit of detection:
The limit of detection for Magnesium is 0.05 mEq/L.

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

Precision:
Precision studies were performed with two controls using NCCLS protocol EP5-A. The results of the precision studies are shown below:

Sample	Within-run		Between-run		Total	
	Mean	CV%	Mean	CV%	Mean	CV%
Control 1	1.94	4.20	1.96	3.47	3.90	7.67
Control 2	3.51	2.99	1.79	3.15	5.3	6.14

Method comparison:
Comparative studies were done to compare our reagent with another commercial Magnesium Assay. No significant differences were observed. Details of the comparative studies are available on request.

REFERENCE RANGE

Serum	(Children)	:	1.5 - 2.0 mEq/L
	(Adults)	:	1.3 - 2.5 mEq/L
CSF		:	2.0 - 3.0 mEq/L
Urine		:	6.0 - 8.5 mEq/24 hrs

It is recommended that each laboratory establish its own normal range representing its patient population*.
Note : 2 mEq/L = 1 mmol/L = 2.44 mg/dl

NOTE

Magnesium is reported to be stable in serum / plasma for 7 days at 2-8°C. All glassware being used for the test should first be rinsed with 1 % or 0. 1 N HCl and then with good quality deionised water before use.
Chelating agents such as EDTA, Oxalate and Citrate, present even in traces, prevent the formation of the colour complex, hence necessary care should be taken during the assay.
RBC's have double the magnesium content compared to serum, and hence haemolysed samples should not be used. The reagent may be used in several automated analyzers. Instructions are available on request.
Standard is traceable to standard reference material (SRM) 909b.
Do not use turbid, deteriorated or leaking reagents.

REFERENCES

1. Gindler, E., et. al. (1971), Clin. Chem. 17: 662.
2. Clinical Chemistry, Principles, Procedures, Correlations, Michael L. Bishop, et.al., 5th Edition.

Mfd. for:

Singapore Biosciences PTE Ltd.

11 Yishun Street 51, # 04-23, The Criterion, Singapore 767971.

EC REP

CMC Medical Devices & Drugs S.L.,
C/ Horacio Lengo No. 18, CP 29006, Malaga, Spain.

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