BIOLABO
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MANUFACTURER:
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MAGNESIUM CALMAGITE

Reagent for quantitative determination of magnesium in human serum and plasma or urines.

I REF K1212	**R1**	4 x 17 mL
I REF K2212	**R1**	4 x 25 mL

TECHNICAL SUPPORT AND ORDERS
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Latest revision: www.biolabo.fr

CE

IVD

Made In France

I: corresponds to significant modifications

I INTENDED USE

This reagent is designated for professional use in laboratory (automated method).
It allows the quantitative determination of magnesium in human serum and plasma or urines.

I GENERALITIES (1)

Adult human body (70 Kg) contains 21 to 28 g of magnesium. Of this, about 60% is in bone, 20% in skeletal muscle, 19% in other cells, and about 1% in the extracellular fluids. About 30% of magnesium in plasma is associated with proteins (primarily albumin). Consequently, a change in the concentration in albumin can affect the concentration in magnesium.
Hypomagnesaemia may be a secondary effect in hypocalcemic or calcium-deficient tetany. Conditions that have been associated with hypomagnesemia include chronic alcoholism, childhood malnutrition, lactation, malabsorption, acute pancreatitis, hypothyroidism, chronic glomerulonephritis, aldosteronism, digitalis intoxication and prolonged intravenous feeding.
Hypermagnesemia have been observed in dehydration, severe diabetic acidosis, and immediately following myocardial infarction.

PRINCIPLE (1) (4) (5)

Gindler, Heth and Khayam-Bashi method. Calmagite, a metallochromic indicator (1 -[1-hydroxy-4-methyl-2-phenylazo]-2-naphtol-4-sulfonic acid), forms in basic buffered medium a colored complex with the magnesium. The absorbance, measured at 510-550 nm, is proportional to the concentration of magnesium in the specimen. EGTA reduces Calcium interference, Potassium cyanide (KCN) reduces interference of heavy metals and a surfactant reduces the interference of proteins and lipemia.

REAGENTS

R1 **MG2** Calmagite reagent

KCN	6.14 mmol/L
EGTA	250 µmol/L
Calmagite	≥ 100 µmol/L
AMP	≥ 100 mmol/L
Surfactant	

According to 1272/2008/EC regulation, this reagent is not classified as dangerous.

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

I Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Ready for use.

STABILITY AND STORAGE

Stored away from light, well caped in the original vial at 18-25°C, when stored and used as described, reagents are stable:

Unopened:

- Until expiry date stated on the label.

Once opened:

- Reagent is stable at least 6 months.
- Discard any cloudy reagent or if absorbance at 546 nm < 0.600 or >1.200.

SPECIMEN COLLECTION AND HANDLING (2)

Collect in a metal-free container and without preservatives

Unhemolysed serum or heparinized plasma: Collect on fasting. Avoid oxalate, citrate or EDTA. Separate red cells immediately.

Magnesium is stable for several days in serum at 2-8°C.

24h urines (acidified pH 1.0): dilute (1+4) with demineralized water before assay.

LIMITS (3)

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Biochemistry Clinical Analyzer Kenza One, Kenza 240TX/ISE or Kenza 450TX/ISE

EXPECTED VALUES (2)

Serum or Plasma	mg/dL	[mmol/L]
Newborn	1.5-2.2	[0.62-0.91]
Child	1.7-2.2	[0.70-0.91]
Adult	1.6-2.6	[0.66-1.07]
Urines	73-122 mg/24h	[3.00-5.00 mmol/24 h]

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES

ON Kenza 240TX, at 37°C, 546 nm

Linearity Range: between 0.7 mg/dL (LQ) and 9.2 mg/dL

Detection limit: approx. 0.13 mg/dL

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High Level*
Mean (mg/dL)	1.08	2.22	3.91
S.D. mg/dL	0.03	0.04	0.07
C.V. %	2.7	2.0	1.7

Between Run N = 20	*Low level*	*Normal level*	*High level*
Mean (mg/dL)	1.09	2.21	3.7
S.D. mg/dL	0.04	0.05	0.1
C.V. %	3.7	2.3	2.7

Comparison studies with commercially available reagent:

Realized in clinical environment on specimens between 0.7 and 2.7 mg/dL (n=76):

y = 0.986 x + 0.00188 r = 0.9804

Analytical sensitivity: approx. 0.067 abs for 1 mg/dL

Interferences:

Turbidity	Positive interference from 0.081 abs
Total bilirubin	Positive interference from 432 µmol/L
Direct bilirubin	No interference up to 373 µmol/L
Ascorbic acid	No interference up to 2500 mg/dL
Glucose	No interference up to 1088 mg/dL
Hemoglobin	Positive interference from 86 µmol/L

Other substances may interfere (see § Limits)

On the board stability: 8 days

Calibration Stability: 8 days

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations.

Performances and stability data on Kenza 450TX/ISE and Kenza One are available on request.

CALIBRATION (6)

- REF 95015 Multicalibrator traceable to *SRM 909*.

The calibration frequency depends on proper instrument functions and on preservation of the reagent.

QUALITY CONTROL

- REF 95010 EXATROL-N Level I
- REF 95011 EXATROL-P Level II
- REF 95012 Urinary Controls
- External quality control program

It is recommended to control in the following cases:

- At least once a run
- At least once within 24 hours
- When changing vial of reagent
- After maintenance operations on the instrument

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test
2. If control is still out of range, use a new vial of fresh calibrator
3. If control is still out of range, use a new vial of reagent and reassay

If control is still out of range, please contact BIOLABO technical support or your local Agent.

PROCEDURE

Refer to validated application of the Kenza Analyzer used

CALCULATION

The analyzer provides directly final result.
Refer to the instruction of use of Kenza analyzer.

REFERENCES

(1) TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p.1034-1036 et 1408-1410.
(2) Clinical Guide to Laboratory Test, 3rd Ed., N.W. TIETZ (2006) p. 706-711
(3) YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p. 3-410 to 3-414
(4) GINDLER E.M., HETH D.A., Clin. Chem. (1971), 17, p.662
(5) H. KHAYAM-BASHI, TSAN Z. LIU, VERN W. Clin. Chem. (1977), 23/2, p.289-291
(6) SRM: Standard Reference Material ®

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute wih