MAGNESIUM
COLORIMETRY

Intended use:
In vitro test for the quantitative determination of magnesium in human serum, plasma and urine.

Summary:

Magnesium is one of the major intracellular cations in the body. Its action is closely related to that of calcium. Magnesium deficiency, hypomagnesaemia can result in various neuromuscular disorders, weakness, tremors, tetany and convulsions. It is associated with hypocalcaeia, intravenous therapy, diabetes mellitus, alcoholism, dialysis and pregnancy. Increased serum magnesium levels are associated with dehydration, severe diabetic acidosis and Addison's Disease. Conditions that interfere with glomerular filtration as in renal failure result in retention of magnesium and hence elevation of serum levels.

Test principles:

Magnesium ions react with xylidyl blue in an alkaline medium to form a water soluble purple-red chelate, the colour intensity of which is proportional to the concentration of magnesium in the sample. Calcium is excluded from the reaction by complexing with EGTA.

Reagent concentration:

R1:		
Tris Buffer	0.2 mmol/L	
Xylidyl Blue	0.1 mmol/L	pH 10.7
K_2CO_3	77 mmol/L	
EGTA	40 µmol/L	
Stabilizer		

Preparation and stability:

All reagents are ready to use.
Stable up to expiry date when stored at 2-8 °C.
The reagents are stable for 1 month after opening and kept at 2-8°C.

Interference:

The following analyze were tested up to the levels indicated and found not to interfere:
Hemoglobin: 500 mg/dl
Intralipid: 100 mg/dl
Total Bilirubin: 90 mg/dl
Ascorbic Acid: 45 mg/dl
Ca^{2+}: 4 mmol/l

Testing procedure:

Applications for automated systems are available on request.

Materials provided

• Working solutions as described above.

Additional materials required

• Calibrators and controls as indicated below
• 0.9% NaCl

Wavelength:	505 nm
Assay mode:	End , 0 – 27
Sample:	3 uL
Reagent:	300 uL
Mix, and incubate 5 minutes at 37°	
Measure final absorbance of the sample and standard against the reagent blank.	
Calculation:	
Asample Acalibrator x Calibrator conc. = Magnesium conc.	

Sensitivity

The minimum detectable level has been determined as 0.061 mmol/L.

LINEARITY

The method is linear up to 3.04 mmol/L. If the samples above this concentration should be diluted 1:1 with 0.9% NaCl and repeat assay. Multiply the result by 2.

Reference values:

Serum: 0.7-1.1 mmol/L.

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

Precision

The CV of the test should be ≤ 5 %

Inter Assay Precision		
N= 20	**Level 1**	**Level 2**
Mean (mmol/L)	0,93	1,84
SD	0,012	0,016
CV	1,27 %	0,89 %
Inter Assay Precision		
N= 5	**Level 1**	**Level 2**
Mean (mmol/L)	0,96	1,82
SD	0,015	0,033
CV	1,57 %	1,81 %

Correlation

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:
y = 0.969x+0.0383,
R^2=0.9946; 110 patient samples were analyzed.

Quality Control:

BIOCON N	5 x 5 ml	#B10814
BIOCON P	5 x 5 ml	#B10817

The control intervals and limits must be adapted to the individual laboratory and country-specific requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Calibration:

S1: 0.9% NaCl
S2: BIOCAL H 5 x 3 ml #B11895

Calibration frequency:

A two-point-calibration is recommended in case of:
1-change of lot
2- quality control requirements

Order Information

Cat No.	Pack.	Cat No.	Pack.	Cat No.	Pack.
CC455	2x115 mL	KL440	5x75 mL	BMAG500	5x100 mL
OL455	6x60 mL	SH455	4x90 mL	BMAG250	5x50 mL
AB455	5x100 mL	CR455	Cartridget	BMAG125	5x25 mL

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. Solution contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

ISO 9001:2015
ISO 13485:2016

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REFERENCES

1. Kolthoff, I. M., Biochem. Z., 186, 344 (1927).
2.Pesce, A.J. and Kaplan, L.A., Methods in Clinical Chemistry, C.V. Mosby Co., St. Louis, 1987.
3.Greenberg, D. M., and Mackey, M. A., J. Biol. Chem., Q&419 (1932).

Manufacturer
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SYMBOLS

IVD	for in vitro diagnostic use only
LOT	lot of manufacturing
REF	code number
	storage at temperature interval
	expiration date (year/month)
	warning, read enclosed documents
	Read the directions