Magnesium XL FS*

Diagnostic reagent for quantitative in vitro determination of magnesium in serum, plasma or urine on BioMajesty JCA-BM6010/C

Order Information

Cat. No. 1 4610 99 10 961
6 x 160 tests

Method

Photometric test using xylidyl blue

Principle

Magnesium ions form a purple colored complex with xylidyl blue in alkaline solution. In presence of GEDTA, which complexes calcium ions, the reaction is specific. The intensity of the purple color is proportional to the magnesium concentration.

Reagents

Components and Concentrations

Ethanolamine	pH 11.0	750 mmol/L
GEDTA (Glycoletherdiamine tetraacetic acid)		60 µmol/L
Xylidyl blue		110 µmol/L

Storage Instructions and Reagent Stability

The reagent is stable up to the end of the indicated month of expiry, if stored at 2 – 8 °C and contamination is avoided. Do not freeze the reagent!

Warnings and Precautions

1. Reagent: Danger. H315 Causes skin irritation. H318 Causes serious eye damage. P264 Wash hands and face thoroughly after handling. P280 Wear protective gloves / protective clothing / eye protection. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a poison center or doctor/physician.
2. In very rare cases, samples of patients with gammopathy might give falsified results [8].
3. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
4. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagent is ready to use. The bottles are placed directly into the reagent trays.

Specimen

Serum, plasma or urine (do not use EDTA plasma!)

Stability [1]:

in serum/plasma	7 days	at	20 – 25°C
	7 days	at	4 – 8°C
	1 year	at	–20°C
In urine:	3 days	at	20 – 25°C
	3 days	at	4 – 8°C
	1 year	at	–20°C

Acidify urine with some drops of conc. HCl to pH 3 – 4. Dilution 1 + 4 with water is automatically done by the instrument.

Freeze only once.
Discard contaminated specimens.

Calibrators and Controls

For calibration, DiaSys TruCal U calibrator is recommended. For internal quality control DiaSys TruLab N and P or TruLab Urine controls should be assayed. The assigned values of the calibrator have been made traceable to the reference method Atomic Absorption Spectrometry (AAS). Each laboratory should establish corrective action in case of deviations in control recovery.

		Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL
TruLab Urine Level 1	5 9170 99 10 062	20 x 5 mL
	5 9170 99 10 061	6 x 5 mL
TruLab Urine Level 2	5 9180 99 10 062	20 x 5 mL
	5 9180 99 10 061	6 x 5 mL

Performance Characteristics

Measuring range up to 5 mg/dL (2 mmol/L) magnesium (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	0.03 mg/dL (0.012 mmol/L) magnesium
On-board stability	4 weeks
Calibration stability	12 days

Interferences < 10% by
Ascorbate up to 30 mg/dL
Bilirubin (conjugated and unconjugated) up to 60 mg/dL
Calcium up to 25 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL
Hemolysis interferes because magnesium is released by erythrocytes [2]
For further information on interfering substances refer to Young DS [7].

Precision (Serum)			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	1.46	2.95	4.28
Mean [mmol/L]	0.60	1.21	1.76
Coefficient of variance [%]	1.31	0.80	0.98
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	2.20	4.12	4.59
Mean [mmol/L]	0.90	1.69	1.89
Coefficient of variance [%]	1.32	1.00	0.99

Method comparison (Serum; n=95)	
Test x	Competitor Magnesium
Test y	DiaSys Magnesium XL FS
Slope	0.942
Intercept	0.058 mmol/L (0.141 mg/dL)
Coefficient of correlation	r = 0.992

Precision (Urine)			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	2.93	6.19	10.0
Mean [mmol/L]	1.20	2.55	4.13
Coefficient of variance [%]	1.16	1.31	0.52
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	2.95	6.13	10.1
Mean [mmol/L]	1.21	2.52	4.17
Coefficient of variance [%]	1.44	0.97	1.16

Method comparison (Urine; n=40)	
Test x	Competitor Magnesium
Test y	DiaSys Magnesium XL FS
Slope	0.982
Intercept	–0.053 mg/dL (–0.0217 mmol/L)
Coefficient of correlation	0.9996

** lowest measurable concentration which can be distinguished from zero mean + 3 SD (n=20) of an analyte free specimen

Conversion factor

Magnesium [mg/dL] x 0.4114 = Magnesium [mmol/L]
Magnesium in Urine [mg/24 h] x 0.0411 = Magnesium [mmol/24 h]

Reference Range [2,3]

Serum/Plasma:

Neonates	1.2 – 2.6 mg/dL	(0.48 – 1.05 mmol/L)
Children	1.5 – 2.3 mg/dL	(0.60 – 0.95 mmol/L)
Women	1.9 – 2.5 mg/dL	(0.77 – 1.03 mmol/L)
Men	1.8 – 2.6 mg/dL	(0.73 – 1.06 mmol/L)

Urine: 73 – 122 mg/24 h (3 – 5 mmol/24 h)

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Guder WG, Zatwa B et al. The quality of Diagnostic Samples. 1st ed. Darmstadt: Git Verlag, 2001: 38-39, 50-51.
2. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 339-40.
3. Sitzmann FC. Normalwerte. München: Hans Marseille Verlag GmbH: 1986. p. 166.
4. 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.
5. Mann CK, Yoe JH. Spectrophotometric determination of magnesium with 1-Azo-2-hydroxy-3-(2.4-dimethylcarboxanilido)-naphthalene-1'-(2-hydroxybenzene). Anal Chim Acta 1957; 16 : 155-60.
6. Bohoun C. Microdosage du magnesium dans divers milieux biologiques. Clin Chim Acta 1962; 7: 811-7.
7. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240–1243.

Manufacturer

IVD CE

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BioMajesty

Magnesium XL FS

Chemistry code 10 461

Application for serum, plasma, CSF, urine samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	100
R2e volume	0
R2 volume	0
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1
Sample vol (U)	1
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	MG
Digits	2
M-wave L.	545
S-wave.L	694
Analy.mthd.	EPA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	1	1
Diluent method	No dil	With dil
Undil. sample vol.	0	10
Diluent volume	0	40
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	0
S-DET.P.r	0
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999