

MAGNESIUM

Cat. No.	Pack Name	Packaging (Content)
XSYS0040	MG 88	2 x 44 ml



Stability

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

Discard contaminated specimens.

Acidify urine with some drops of conc. HCl to pH 3-4, then dilute 1+4 with dist. water; multiply the result by 5.

CALIBRATION

Calibration with calibrator XL MULTICAL, Cat. No. XSYS0034 is recommended.

QUALITY CONTROL

For quality control ERBA NORM, Cat. No. BLT00080 and ERBA PATH, Cat. No. BLT00081 are recommended.

CALCULATION

The XL Results are calculated automatically by the instrument

UNIT CONVERSION

mg/dl x 0.4114 = mmol/l

EXPECTED VALUES ⁶

Serum or plasma	
Newborn, 2 - 4 d	1.5 – 2.2 mg/dl
5 mo – 6 y	1.7 – 2.3 mg/dl
6 – 12 y	1.7 – 2.1 mg/dl
> 12 y	1.6 – 2.6 mg/dl
CSF	2.1 – 3.3 mg/dl
Urine	12 – 291 mg / 24 h

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

PERFORMANCE DATA

Limit of quantification:	0.16 mg/dl
Linearity:	5.85 mg/dl

Intra-assay precision Within run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	3.305	0.122	3.66
Sample 2	5.854	0.120	2.04

Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	2.341	0.039	1.65
Sample 2	4.634	0.095	2.05

COMPARISON

A comparison between XL-Systems Magnesium (y) and a commercially available test (x) using 40 samples gave following results:

$$y = 1.014x - 0.005 \text{ mg/dl}$$

$$r = 0.995$$

INTERFERENCES

Following substances do not interfere: bilirubin up to 40 mg/dl, triglycerides up to 2000 mg/dl. Haemoglobin interferes because magnesium is released by erythrocytes.

WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. To be handled by entitled and professionally educated person.

Reagent of the kit is not classified like dangerous.

The product can cause irritation of the eyes.

S 25 Avoid contact with eyes.

WASTE MANAGEMENT

Please refer to local legal requirements.

INTENDED USE

Diagnostic reagent for quantitative *in vitro* determination of Magnesium in human serum, plasma, cerebrospinal fluid and urine.

CLINICAL SIGNIFICANCE

Magnesium is an essential nutrient which is involved in many biochemical functions. It has a structural role in nucleic acids and ribosomal particles, required as an activator for many enzymes and has a role in energy producing oxidative phosphorylation.

Hypomagnesaemia results in the impairment of neuromuscular functions and may develop in severe prolonged diarrhoea, malabsorption syndromes, primary aldosteronism and diuretic therapy. Hypermagnesaemia is seen in renal glomerular failure and diabetic coma.

PRINCIPLE

Magnesium reacts with Xylidyl Blue to form a colored compound in alkaline solution. The intensity of the colour formed is proportional to the magnesium concentration in the sample. Interference with calcium is prevented by the use of GEDTA.

REAGENT COMPOSITION

Xylidyl Blue (I)	110 µmol/l
Ethanolamine	1 mol/l
GEDTA	60 µmol/l

REAGENT PREPARATION

Reagents are liquid, ready for use.

STABILITY AND STORAGE

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2–8°C.

SAMPLE PREPARATION

Urine: Acidify urine with some drops of conc. HCl to pH 3-4 then dilute 4+1 with distilled water.

SPECIMEN COLLECTION & HANDLING

It is recommended to follow NCCLS procedures (or similar standardized conditions).

Serum, plasma, cerebrospinal fluid (CSF) or urine. Do not use EDTA plasma.

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485



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ASSAY PARAMETERS

Instrument	XL-100 EM-100	XL-200 EM-200	XL-300/600 EM-360	XL- 640	XL-1000
Test Details					
Test	MGXB	MGXB	MGXB	MGXB	MGXB
Test Code	60	60	60	60	60
Report Name	Magnesium	Magnesium	Magnesium	Magnesium	Magnesium
Unit	mg/dl	mg/dl	mg/dl	mg/dl	mg/dl
Decimal Places	2	2	2	2	2
Wavelength-Primary	505	505	505	505	505
Wavelength-Secondary	0	0	0	0	0
Assay type	1 Point	1 Point	1 Point	1 Point	1 Point
Curve type	Linear	Linear	Linear	Linear	Linear
M1 Start	0	0	0	0	0
M1 End	0	0	0	0	0
M2 Start	32	34	48	60	29
M2 End	34	36	51	63	31
Sample replicates	1	1	1	1	1
Standard replicates	3	3	3	3	3
Control replicates	1	1	1	1	1
Control interval	0	0	0	0	0
Reaction Direction	Incr	Incr	Incr	Incr	Incr
React. Abs. Limit	0	0	0	0	0
Prozone Limit %	0	0	0	0	0
Prozone Check	Lower	Lower	Lower	Lower	Lower
Linearity Limit %	0	0	0	0	0
Delta Abs/Min	0	0	0	0	0
Technical Minimum	0	0	0	0	0
Technical Maximum	5.85	5.85	5.85	5.85	5.85
Y=aX+b					
a=	1	1	1	1	1
b=	0	0	0	0	0
Reagent Abs Min	NA	NA	NA	NA	NA
Reagent Abs Max	NA	NA	NA	NA	NA
Auto Rerun	No	No	No	No	No
Total Reagents	1	1	1	1	1
Reagent R1	MGXB R1	MGXB R1	MGXB R1	MGXB R1	MGXB R1
Reagent R2	NA	NA	NA	NA	NA
Test Volumes					
Test	MGXB	MGXB	MGXB	MGXB	MGXB
Sample Type	SERUM	SERUM	SERUM	SERUM	SERUM
Sample Volumes					
Normal	2	2	3	2	2
Dilution Ratio	1	1	1	1	1
Increase	8	8	8	8	8
Dilution Ratio	1	1	1	1	1
Decrease	2	2	2	2	2
Dilution Ratio	5	5	5	5	5
Standard volume	2	2	3	2	2
Reagent Volumes and Stirrer speed					
RGT-1 Volume	200	200	300	200	200
R1 Stirrer Speed	High	High	High	High	High
RGT-2 Volume	0	0	0	0	0
R2 Stirrer Speed	NA	NA	NA	NA	NA
RGT-3 Volume	0	0	0	0	0
R3 Stirrer Speed	NA	NA	NA	NA	NA
Reference Ranges					
Test	MGXB	MGXB	MGXB	MGXB	MGXB
Sample Type	SERUM	SERUM	SERUM	SERUM	SERUM
Reference Range	Default	Default	Default	Default	Default
Category Male					
Normal-Lower Limit	1.8	1.8	1.8	1.8	1.8
Normal-Upper Limit	2.6	2.6	2.6	2.6	2.6
Panic-Lower Limit	NA	NA	NA	NA	NA
Panic-Upper Limit	NA	NA	NA	NA	NA
Category Female					
Normal-Lower Limit	1.9	1.9	1.9	1.9	1.9
Normal-Upper Limit	2.5	2.5	2.5	2.5	2.5
Panic-Lower Limit	NA	NA	NA	NA	NA
Panic-Upper Limit	NA	NA	NA	NA	NA

REFERENCES

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 231-41.
2. 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.
3. Mann CK, Yoe JH. Spectrophotometric determination of magnesium with 1-Azo-2-hydroxy-3-(2,4-dimethyl-carboxanilido)-naphthalene-1'-(2-hydroxybenzene). Anal Chim Acta 1957;16:155-60.
4. Bohoun C. Microdosage du magnesium dans divers milieux biologiques. Clin Chim Acta 1962;7:811-7.
5. Sitzmann FC. Normalwerte. München: Hans Marseille Verlag GmbH: 1986. p. 166.
6. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. Burtis, C.A., Ashwood, E.R., Bruns, D.E.; 5th edition, WB Saunders Comp., 2012.

SYMBOLS USED ON LABELS



Catalogue Number



Manufacturer



See Instruction for Use



Lot Number



CE Mark - Device comply with the Directive 98/79/EC



Storage Temperature



Expiry Date



In Vitro Diagnostics



Content

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485



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