respons®920

Magnesium XL FS*

Diagnostic reagent for quantitative in vitro determination of magnesium in serum or plasma on DiaSys respons®920

Order Information

Cat. No. 1 4610 99 10 921
4 containers for 120 determinations each

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. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
3. In very rare cases, samples of patients with gammopathy might give falsified results [8].
4. 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.
5. 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 rotor.

Specimen

Serum or plasma (do not use EDTA plasma!)

Stability [1]:

7 days	at	20 – 25°C
7 days	at	4 – 8°C
1 year	at	–20°C

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

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

	Cat. No.	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

Performance Characteristics

Measuring range up to 5 mg/dL 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**	0.2 mg/dL magnesium
On-board stability	3 weeks
Calibration stability	3 weeks

Interferences < 10% by
Ascorbate up to 30 mg/dL
Bilirubin up to 40 mg/dL
Calcium up to 25 mg/dL
Lipemia (triglycerides) up to 1600 mg/dL
Hemolysis interferes because magnesium is released by erythrocytes [2].
For further information on interfering substances refer to Young DS [2].

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	1.79	2.84	4.53
Coefficient of variance [%]	2.59	2.75	1.53
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	1.90	2.67	4.78
Coefficient of variance [%]	4.13	2.48	2.48

Method comparison (n=120)	
Test x	DiaSys Magnesium XL FS (Hitachi 917)
Test y	DiaSys Magnesium XL FS (respons®920)
Slope	1.02
Intercept	-0.0525 mg/dL
Coefficient of correlation	0.998

** 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]

Reference Range [3]

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)

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.
2. 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.
3. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 339-40.
4. Sitzmann FC. Normalwerte. München: Hans Marseille Verlag GmbH: 1986. p. 166.
5. 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.
6. 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.
7. Bohoun C. Microdosage du magnesium dans divers milieux biologiques. Clin Chim Acta 1962; 7: 811-7.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

* fluid stable

respons®920

DiaSys Diagnostic Systems

Magnesium XL FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	MG				Auto Rerun		☐
Report Name	:	Magnesium XL				Online Calibration		☐
Unit	:	mg/dL	Decimal Places	:	2	Cuvette Wash		☐
Wavelength-Primary	:	546	Secondary	:	700	Total Reagents	:	1
Assay Type	:	1-Point	Curve Type	:	Linear	Reagent R1	:	MG R1
M1 Start	:	0	M1 End	:	0	Reagent R2	:	
M2 Start	:	33	M2 End	:	33			
Sample Replicates	:	1	Standard Replicates	:	3	Consumables/Calibrators:		
Control Replicates	:	1	Control Interval	:	0	Blank/Level 0	:	*
Reaction Direction	:	Increasing	React. Abs. Limit	:	0.0000	Calibrator 1	:	*
Prozone Limit %	:	0	Prozone Check	:	Lower			
Linearity Limit %	:	0	Delta Abs./Min.	:	0.0000			
Technical Minimum	:	0.20	Technical Maximum	:	5.00			
Y = aX + b a=	:	1.0000	b=	:	0.0000			

* Enter calibrator value.

Test Details			Test Volumes		Reference Ranges
Test	:	MG			
Sample Type	:	Serum			

Sample Volumes

Normal	:	2.00 µL	Dilution Ratio	:	1 X
Increase	:	6.00 µL	Dilution Ratio	:	1 X
Decrease	:	2.00 µL	Dilution Ratio	:	2 X
Standard Volume	:	2.00 µL			

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	180 µL	R1 Stirrer Speed	:	High
RGT-2 Volume	:	0 µL	R2 Stirrer Speed	:	0

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	MG		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (mg/dL)	Upper Limit (mg/dL)
Normal	:	1.80	2.60
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other