respons®910

Magnesium XL FS*

Order Information

Cat. No.	Kit size
1 4610 99 10 921	Σ 480 (4 x 120)

Intended Use

Diagnostic reagent for quantitative in vitro determination of magnesium in human serum or heparin plasma on automated respons®910.

Summary

The essential trace element magnesium is the fourth most common cation in the human body and the second most common intracellular cation. It is mainly localized in the skeletal system (53%), muscles (27%) and in non-muscular tissue (19%). Only 1% of the total body magnesium stores is located in extracellular fluid [1]. Magnesium is a pivotal cofactor in many enzymatic processes. Furthermore, it is important in processes like oxidative phosphorylation, glycolysis, cell replication, nucleotide metabolism and protein biosynthesis [2]. Deficiency of magnesium is a quite common disorder, which can be caused by malnutrition, malabsorption, renal loss and endocrinological disturbances. Complications associated with decreased magnesium concentrations are neuromuscular irritability (e.g. tremor, seizures) and cardiac symptoms (e.g. tachycardia, arrhythmia). Decreased magnesium concentrations are often related to decreased calcium and potassium levels, taking into account that hypomagnesemia may be the primary cause of hypocalcemia. Elevated magnesium values can be observed in dehydration, renal disorders and after intake of excessive amounts of antacids. Additionally, enhanced magnesium concentrations can be associated with weakness of reflexes and low blood pressure [1,2].

Method

Photometric test using xylidyl blue

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
Glycoletherdiamine-tetraacetic acid	(GEDTA)	60 µmol/L
Xylidyl blue		110 µmol/L

Storage and Stability

Reagent is stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze.

The open-vial stability of the reagent is 18 months until expiry date.

Warnings and Precautions

1. Components contained in Magnesium XL FS are classified according to EC regulation 1272/2008 (CLP) as follows:

⚠ Reagent: Danger. Contains Ethanolamine. 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/doctor.

2. In very rare cases, samples of patients with gammopathy might give falsified results [3].
3. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
4. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
5. Please refer to the safety data sheets (SDS) 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.
6. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

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

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [4]:

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

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the reference method Atomic Absorption Spectrometry (AAS). Use TruLab N and TruLab P for internal quality control. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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 from 0.2 mg/dL up to 5 mg/dL, linearity is given within ± 5%.
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
Limit of quantitation**	0.2 mg/dL
Onboard stability	10 days
Calibration stability	7 days

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ascorbic acid	30 mg/dL	3.39
Bilirubin (conjugated)	50 mg/dL	2.04
	50 mg/dL	2.91
Bilirubin (unconjugated)	60 mg/dL	2.08
	60 mg/dL	2.99
Calcium	20 mg/dL	2.08
Hemolysis	250 mg/dL	1.90
	250 mg/dL	2.90
Lipemia (triglycerides)	1300 mg/dL	1.99

	1800 mg/dL	2.78
For further information on interfering substances, refer to the literature [5-7].		

Precision			
Repeatability (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	2.20	3.77	4.73
CV [%]	2.41	2.36	1.68
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	1.96	2.40	4.84
CV [%]	3.01	2.46	1.75

Method comparison (n=113)	
Test x	DiaSys Magnesium XL FS (Hitachi 917)
Test y	DiaSys Magnesium XL FS (respons®910)
Slope	1.06
Intercept	-0.099 mg/dL
Coefficient of correlation	0.991

** according to CLSI document EP17-A, Vol. 24, No. 34

Conversion Factor
Magnesium [mg/dL] x 0.4114 = Magnesium [mmol/L]

Reference Range

Serum/Plasma [1]:

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. Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2023 [cited 2024 03 05]. Available from: https:// www.clinical-laboratory-diagnostics.com
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.
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4. W.G. Guder, F. da Fonseca-Wollheim,W. Heil, et al. Quality of Diagnostic Samples. German Society for Clinical Chemistry and Laboratory Medicine. 3rd completely revised edition 2010.
5. 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.
6. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, https://clinfx.wiley.com/ aaccweb/aacc/, accessed in March 2024. Published by AACC Press and John Wiley and Sons, Inc.
7. Sonntag O, Scholer A. Drug interference in clinical chemistry: recommendation of drugs and their concentrations to be used in drug interference studies. Ann Clin Biochem. 2001 Jul;38:376-85.

Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.

IVD CE

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* Fluid Stable

respons®910

Magnesium XL FS

Application for serum and plasma 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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	MG
Shortcut:	
Reagent barcode reference:	047
Host reference:	047

Technic	
Type:	End point
First reagent:[µL]	180
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	
Blank reagent	
Sensitive to light	
Main wavelength:[nm]	546
Secondary wavelength:[nm]	700
Polychromatic factor:	1.0000
1 st reading time [min:sec]	(-00:12)
Last reading time [min:sec]	06:00
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	0.2000
Concentration technical limits-Upper	5.0000
SERUM	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
URINE	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6

Results	
Decimals	2
Units	mg/dL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	Male
Age	
SERUM	>=1.80 <=2.60
URINE	
PLASMA	>=1.80 <=2.60
CSF	
Whole blood	
Gender	Female
Age	
SERUM	>=1.90 <=2.50
URINE	
PLASMA	>=1.90 <=2.50
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
	Max delta abs.
Cal. 1	0.003
Cal. 2	0.010
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.80

Calculations	
Model	X
Degree	1

* Enter calibrator value