Magnesium XL FS*

Order Information

Cat. No.	Kit size	
1 4610 99 10 021	6 x	25 mL
1 4610 99 10 026	6 x	100 mL
1 4610 99 10 704	8 x	50 mL
1 4610 99 10 930	6 x	20 mL

Kits for use in conjunction with DiaSys CE applications.

Intended Use

Diagnostic reagent for quantitative in vitro determination of magnesium in human serum, heparin plasma or urine on automated photometric systems.

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.

Materials Required

General laboratory equipment

Specimen

Human serum, heparin plasma or urine

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

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

Stability in serum/plasma [4]:

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

Stability in urine [4]:

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, then dilute 1+4 with dist. water; multiply the result by 5.

Only freeze once. Discard contaminated specimens.

Assay Procedure

Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	545/694 nm
Temperature	37°C
Measurement	Endpoint
Sample/Calibrator	1.0 µL
Reagent	100 µL
Addition reagent	Cycle 19 (286 s)
Absorbance	Cycle 41/42 (586 s/600 s)
Calibration	Linear

Calculation

With Calibrator

$$\text{Magnesium [mg/dL]} = \frac{\text{A Sample}}{\text{A Cal.}} \times \text{Conc. Cal. [mg/dL]}$$

Conversion Factor

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

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the reference method Atomic Absorption Spectrometry (AAS). Magnesium Standard FS may be used alternatively for calibration. Use TruLab N and TruLab P or TruLab Urine Level 1 and Level 2 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
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
Magnesium Standard FS	1 4600 99 10 030	6 x 3 mL

Performance Characteristics

Data evaluated on BioMajesty® JCA-BM6010/C

Serum/Plasma

Measuring range up to 5 mg/dL, linearity is given within ± 5%. When values exceed this range, samples should be diluted 1 + 4 with NaCl solution (9 g/L) and the result multiplied by 5.	
Limit of detection**	0.03 mg/dL

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ascorbic acid	30 mg/dL	2.08
Bilirubin (conjugated)	60 mg/dL	2.08
Bilirubin (unconjugated)	60 mg/dL	2.07
Calcium	25 mg/dL	2.07
Lipemia (triglycerides)	2000 mg/dL	2.15

Hemolysis interferes because magnesium is released by erythrocytes [1].

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]	1.46	2.95	4.28
CV [%]	1.31	0.797	0.979
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	2.20	4.12	4.59
CV [%]	1.32	0.998	0.992

Method comparison (n=95)	
Test x	Competitor Magnesium (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Magnesium XL FS (BioMajesty® JCA-BM6010/C)
Slope	0.942
Intercept	0.141 mg/dL
Coefficient of correlation	0.992

Urine

Precision			
Repeatability (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	2.93	6.19	10.0
CV [%]	1.16	1.31	0.516
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	2.95	6.13	10.1
CV [%]	1.44	0.971	1.16

Method comparison (n=40)	
Test x	Competitor Magnesium (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Magnesium XL FS (BioMajesty® JCA-BM6010/C)
Slope	0.982
Intercept	-0.053 mg/dL
Coefficient of correlation	0.999

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

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
Urine [8]:	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. Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2023 [cited 2024 03 05]. Available from: https:// www.clinical-laboratory-diagnostics.com
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IVD CE

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* Fluid Stable