BioMajesty®

# Magnesium XL FS*

## Order Information

| Cat. No. | Kit size |
|---|---|
| 1 4610 99 10 961 | Σ 960 (6 x 160) |

## Intended Use

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

## 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, 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. Dilution 1 + 4 with water is automatically done by the instrument.

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 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 |

## Performance Characteristics

**Serum/Plasma**

| | |
|---|---|
| Measuring range 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** | 0.03 mg/dL |
| Onboard stability | 4 weeks |
| Calibration stability | 12 days |

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| 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.

**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

**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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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.
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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

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# Magnesium XL FS

### Chemistry code 10 461

## Application for serum, plasma and 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 |