

Magnesium XL FS*

Diagnostic reagent for quantitative in vitro determination of magnesium in serum or plasma on DiaSys respons[®]910

Order Information

Cat. No. 1 4610 99 10 921
4 containers for 120 tests 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 (Glycoetherdiamine tetraacetic acid) | | 60 µmol/L |
| Xylidyl blue | | 110 µmol/L |
| Detergents | | |

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 S25: Avoid contact with eyes.
2. In very rare cases, samples of patients with gammopathy might give falsified results.
3. 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.

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

For calibration, DiaSys TruCal U calibrator is recommended. 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 or use rerun function). | |
| Limit of detection** | 0.2 mg/dL magnesium |
| On-board stability | 10 days |
| Calibration stability | 7 days |

| Interfering substance | Interferences < 10% | Magnesium [mg/dL] |
|--|---------------------|-------------------|
| Ascorbate | up to 30 mg/dL | 3.39 |
| Hemoglobin | up to 250 mg/dL | 1.90 |
| | up to 250 mg/dL | 2.90 |
| Bilirubin, conjugated | up to 50 mg/dL | 2.04 |
| | up to 50 mg/dL | 2.91 |
| Bilirubin, unconjugated | up to 60 mg/dL | 2.08 |
| | up to 60 mg/dL | 2.99 |
| Lipemia (triglycerides) | up to 1300 mg/dL | 1.99 |
| | up to 1800 mg/dL | 2.78 |
| Calcium | up to 20 mg/dL | 2.08 |
| Hemolysis interferes because Magnesium is released by erythrocytes [3]. | | |
| 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] | 2.20 | 3.77 | 4.73 |
| Coefficient of variance [%] | 2.41 | 2.36 | 1.68 |
| Between run (n=20) | Sample 1 | Sample 2 | Sample 3 |
| Mean [mg/dL] | 1.96 | 2.40 | 4.84 |
| Coefficient of variance [%] | 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 NCCLS document EP17-A, vol. 24, no. 34

Conversion factor

Magnesium [mg/dL] x 0.411 = 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.

Manufacturer



DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

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 |
| Name: | MG |
| Shortcut: | |
| Reagent barcode reference: | 047 |
| Host reference: | |

| Technic | |
|---------------------------------------|------------|
| Type: | Endpoint |
| First reagent:[μ L] | 180 |
| Blanc correction | Yes |
| Second reagent:[μ L] | |
| Blanc correction | |
| Main wavelength:[nm] | 546 |
| Secondary wavelength:[nm] | 700 |
| Polychromatic factor: | 1.000 |
| 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 [%] | |

| Sample | |
|--------------------------------------|------|
| Diluent | NaCl |
| Concentration technical limits-Lower | 0.20 |
| Concentration technical limits-Upper | 5.00 |
| SERUM | |
| Normal volume [μ L] | 2 |
| Normal dilution (factor) | 1 |
| Below normal volume [μ L] | 4 |
| Below normal dilution (factor) | 1 |
| Above normal volume [μ L] | 2 |
| Above normal dilution (factor) | 6 |
| URIN | |
| Normal volume [μ L] | 2 |
| Normal dilution (factor) | 1 |
| Below normal volume [μ L] | 4 |
| Below normal dilution (factor) | 1 |
| Above normal volume [μ L] | 2 |
| Above normal dilution (factor) | 6 |
| PLASMA | |
| Normal volume [μ L] | 2 |
| Normal dilution (factor) | 1 |
| Below normal volume [μ L] | 4 |
| Below normal dilution (factor) | 1 |
| Above normal volume [μ L] | 2 |
| Above normal dilution (factor) | 6 |
| CSF | |
| Normal volume [μ L] | 2 |
| Normal dilution (factor) | 1 |
| Below normal volume [μ L] | 4 |
| Below normal dilution (factor) | 1 |
| Above normal volume [μ L] | 2 |
| Above normal dilution (factor) | 6 |

| Results | |
|---------------------------|-------|
| Decimals | 2 |
| Units | mg/dL |
| Correlation factor-Offset | 0.000 |
| Correlation factor-Slope | 1.000 |

| Range | |
|--------|-----------------------|
| Genre | Male |
| Age | |
| SERUM | $\geq 1.80 \leq 2.60$ |
| URINE | |
| PLASMA | $\geq 1.80 \leq 2.60$ |
| CSF | |
| Genre | Female |
| Age | |
| SERUM | $\geq 1.90 \leq 2.50$ |
| URINE | |
| PLASMA | $\geq 1.90 \leq 2.50$ |
| CSF | |

| Contaminants | |
|-------------------|--|
| Contaminant 1 | |
| Wash with | |
| Cycle | |
| Volume [μ L] | |
| Contaminant 2 | |
| Wash with | |
| Cycle | |
| Volume [μ L] | |

| Calibrators details | |
|---------------------|---------------|
| Calibrator list | Concentration |
| Cal. 1 | 0 |
| Cal. 2 | * |
| Cal. 3 | * |
| Cal. 4 | * |
| Cal. 5 | * |
| Cal. 6 | * |
| Max delta abs. | |
| Cal. 1 | 0.015 |
| Cal. 2 | 0.010 |
| Cal. 3 | |
| Cal. 4 | |
| Cal. 5 | |
| Cal. 6 | |
| Drift limit [%] | 0.8 |
| Calculations | |
| Model | X degree |
| Degree | 1 |

* Enter calibrator value