MAGNESIUM XYL

Metodo xvlidvl blue - Endpoint

4 x 25 ml 2 x 100 ml

CL47-100S CL47-200S

INTENDED USE

Kit for quantitative determination of Magnesium in serum, plasma and urine.

CLINICAL MEANING

Magnesium is implied in the process of ATP phosphorylation. ATP is a source of energy for the body, it is therefore present in all metabolic processes and it influences the functions of many organs, including neuromuscular tissue. ATP is especially important for the monitoring of magnesium levels in cardiopatic patients: low levels of magnesium can aggravate cardiac arrhythmia, while higher levels can retard neuromuscular and cardiac conduction.

Magnesium deficit is present in case of malnutrition, malabsorption, lower renal functions such as in hypoparathyroidism, hyperaldosteronism, decompensated diabetes, diuretics usage, alcoholism, preeclampsia. Symptoms of magnesium deficits are mainly neuromuscular: weakness, irritability, convulsions, electrocardiographic alterations etc.

Augmented levels of magnesium are commonly associated with ingestion of hypothyroidism, Addison's disease. Symptoms of higher magnesium levels include lethargy, vomit and nausea.

PRINCIPLE

With xylidyl-blue dye, magnesium ion forms a blue-violet complex, whose color intensity is proportional to the magnesium concentration in the sample.

SAMPLE

Serum, plasma (do not use EDTA).

Avoid hemolyzed samples. STABILITY: 1 week at 2-8°C

24 hour urine adjusted to pH 3-4 with hydrochloric acid. Acidified urine are not suitable for the determination of creatinine.

REAGENTS

Only for In Vitro diagnostics. Liquid monoreagent ready to use.

| Package contents | CL47-100S | CL47-200S |
|--|-----------|------------|
| REAGENT 1 Tampone Tris (pH > 10) 200 mmol/L, xylidyl blue 0,15 mmo/L, EGTA 0,10 mmol/L, detergente. | 4 x 25 ml | 2 x 100 ml |
| STANDARD (Std) Magnesio 2 mEq/L (1 mmol/L) | 1 x 4 ml | 1 x 4 ml |

STABILITY: Store at 2-8°C and protect from light to keep the reagents stable up to the expiration date on the label. Once opened, the reagents are stable for 2 months at 2-8°C if contamination is avoided. Keep bottles closed when not in use. Do not use turbid reagents.

NECESSARY ITEMS – NOT PROVIDED

Usual laboratory equipment: UV/VIS Spectrophotometer with temperature control; automatic micropipettes; Optical glass cuvettes or, alternatively, disposable ones in optical polystyrene; saline solution.

MANUAL ASSAY PROCEDURE

| Method: | increasing endpoint |
|-----------------------|-----------------------|
| Wavelength: | 512 nm (480 - 520) |
| Optical path: | 1 cm |
| Temperature: | 20-37°C |
| Reaction Time: | immediate |
| Reading: | against blank reagent |
| Sample/Reagent Ratio: | 1/100 |
| | |

Bring the reagent to the chosen temperature for the analysis.

Pipette in cuvette:

| | Reagent Blank | Standard | Sample |
|-----------------|---------------|----------|--------|
| Distilled water | 10 µl | - | - |
| Standard | - | 10 µl | - |
| Sample | - | - | 10 µl |
| Reagent 1 | 1,0 ml | 1,0 ml | 1,0 ml |

Stir, then read the absorbance of the standard (AbsStd) and the sample (AbsS) against the blank reagent.

Reaction volumes can be proportionally varied without any change in calculation.

CALCULATION

Calculate the magnesium concentrations in the sample using the following formula:

Serum / plasma:

[mEq/L] magnesium = AbsS / AbsStd x 2

[mEq/L] magnesium = AbsS / AbsStd x 2

[mmol/L] magnesium = AbsS / AbsStd x 1 x L /24h

REFERENCE VALUES

Serum / plasma:

1,4 ÷ 1,9 mEq/L (0,7 ÷ 0,95 mmol/L)

Urine:

Urine[.]

1,3 ÷ 25,0 mEq/24h (0,65 ÷ 12,5 mmol/24h)

Each laboratory should define its own reference values for this method.

QUALITY CONTROL – CALIBRATION

All Clinical Chemistry laboratories should implement a quality control program. Control serums of human origin are available for this purpose on request PRE-NORM serums with normal values PRE-PATH serums with pathological values If the method requires it, a multi-parametric calibrator of human origin is available.

PERFORMANCE CHARACTERISTICS

Sensitivity The sensitivity of the method is 0,05 mEq/L.

Linearity

The method is linear up to 8 mEq/L. For higher values, dilute the sample 1.5 with saline solution and multiply the result bv 5.

Precision

| within run (n=10) | Average [mEq/L] | SD | CV % |
|--------------------|-----------------|------|------|
| Sample 1 | 1,98 | 0,01 | 0,50 |
| Sample 2 | 3,54 | 0,09 | 2,54 |
| | | | |
| between run (n=20) | Average [mEq/L] | SD | CV % |
| Sample 1 | 2,00 | 0,03 | 1,50 |
| Sample 2 | 3,48 | 0,08 | 2,30 |

Interferences

Up to 20 mg/dl of bilirubin does not interfere. Up to 14 mg/dl of calcium does not interfere. Hemolysis presence in the sample gives falsely positive values.

Correlation against a reference method

The correlation of the method (Y) against a reference method (X) gives these equation:

Y = 1,0239 - 0,036 r = 0,9871

DISPOSAL

The product must be disposed of according to national/international laws.

WARNINGS AND PRECAUTIONS

The reagents may contain non-reactive components and various preservatives. Contact with the skin and ingestion should be avoided. Use the normal precautions expected with correct behaviour in laboratory

REFERENCES

- 1 Mann C.K., Yoe J.H., Anal: Chem, 28, 202 (1956)
- 2 Bohuon C., Clin. Chim. Acta 7, 811 (1962)
- 3 Kaplan LA, Pesce AJ: "Clinical Chemistry", Mosby Ed. 1989

MANUFACTURER

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KEY SYMBOLS

| IVD | In Vitro diagnostic medical device |
|------------------|------------------------------------|
| LOT | batch number |
| REF | catalogue number |
| X | temperature limits |
| $\sum_{i=1}^{n}$ | use by |
| \triangle | caution |
| Ĩ | consult accompanying documents |

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