

Magnesium

Xylidyl Blue - EGTA. Colorimetric Liquid

Store at 2 - 25 °C

Configuration

REF	HB0320	HB0320A	HB0320M
VOL	2 x 125 mL	8 x 125 mL	8 x 30 mL
Reagent 1	2 x 125 mL	8 x 125 mL	8 x 30 mL
Standard	1 x 5 mL	4 x 5 mL	-

Intended use

The Cypress Diagnostics kit Magnesium is an in vitro diagnostic medical device intended to be used for the quantitative measurement of magnesium in human serum, heparinized plasma or urine. The device is not automated. The measurement of magnesium is intended to be used for the screening for, aid in diagnosis and monitoring of disorders of magnesium metabolism causing hypomagnesemia or hypermagnesemia. This kit is intended to be used by healthcare professionals in a laboratory-based testing environment. For *in vitro* diagnostic use only. For professional use only.

Clinical significance

Magnesium is one of the most abundant cations in the body and is essential to many physiological processes. Approximately one-half of the body magnesium is present in the bone, most of the remainder is found in soft tissues and blood cells with a small amount present in blood. Decreased levels have been observed in cases of diabetes, alcoholism, diuretics, hyperthyroidism, malabsorption, hyperalimentation, myocardial infarction, congestive heart failure, and liver cirrhosis. Increased magnesium serum levels have been found in renal failure, diabetic acidosis, Addison's disease, and vitamin D intoxication. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Principle

Magnesium ions react with Xylidyl blue in alkaline solution upon which a colored complex is formed. The intensity of the color is proportional to the amount of magnesium present in the sample. Calcium interference is counteracted by complexing with EGTA. ^{Note 5}

Reagent composition

Reagent 1	TRIS buffer pH 11,4 (200 mmol/L) EGTA (0,1 mmol/L) Xylidyl Blue (0,1 mmol/L)
Standard	Magnesium aqueous (see value on label) *BSA (25 g/L)

**This is a material of animal origin, but the risk of this material was assessed as non-hazardous and non-critical in the Risk Analysis*

Precautions

- Reagent 1: H412: Harmful to aquatic life with long lasting effects. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection. P501: Dispose of contents/container in an appropriate container observing applicable local regulations.
- All body fluid samples should be considered potentially infectious materials and the appropriate precautions should be taken. Wear personal protective equipment such as gloves, safety glasses, lab coats or aprons when working with possible biohazard contaminants.
- Use Good Laboratory Practices (GLP) when handling this product.
- Please refer to the MSDS, available on our website, for further information.

Preparation

The reagent and standard are ready to use.

Storage, stability and disposal

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2 - 25 °C.

Handle standard very carefully to prevent contamination. The reagent should be a clear blue solution. If turbidity or precipitation has occurred, the reagent should be discarded.

Do not use the product if deterioration or contamination is suspected or beyond the expiration date or open container stability period. Dispose unused or deteriorated product and waste in compliance with local regulations.

Additional material required but not provided

- Spectrophotometer or colorimeter. Minimum analyzer specifications:
Measuring at 510 nm (500-550)
Linear measuring range: 0 - 2 AU
- Cuvettes, matching the analyzer used (1,0 cm light path)
- General laboratory equipment ^{Note 6}

Samples

Sample type: human serum, heparinized plasma or urine

- Serum, heparinized plasma: free of hemolysis and separated from cells as rapidly as possible. Do not use oxalates, citrate or EDTA as anticoagulant. Stability: 5 days at 4 - 8 °C.

- Urine: collect 24 hours urine specimen in a magnesium free container. Urine should be acidified to pH 1 with HCl. If urine is cloudy, warm the specimen to 60 °C for 10 minutes to dissolve precipitates. Dilute 1:10 with distilled water and multiply the result by 10. Stability: 3 days at 4 - 8 °C.

Procedure

Make sure the reagents and samples are at room temperature.

1. Wavelength 510 nm (500-550); Temperature 37 °C/15-25 °C; Cuvette (1 cm light path).
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

For Blank	1 mL Reagent
For Standard ^{Note 4,7}	10 µL Standard + 1 mL Reagent
For Sample	10 µL Sample + 1 mL Reagent

Mix and read the absorbance (A) after incubation for 3 minutes at 37 °C or 5 minutes at room temperature (15 - 25 °C). Read the absorbance (A) of the samples and standard against blank. The color is stable for at least 45 minutes.

Calculation

Serum and plasma:

$$\text{Magnesium (mg/dL)} = \frac{A_{\text{Sample}} - A_{\text{Blank}}}{A_{\text{Standard}} - A_{\text{Blank}}} \times \text{stand.conc (mg/dL)}$$

Urine (24h):

Magnesium (mg/24h)

$$= \frac{A_{\text{Sample}} - A_{\text{Blank}}}{A_{\text{Standard}} - A_{\text{Blank}}} \times \text{stand.conc} \left(\frac{\text{mg}}{\text{dL}} \right) \times \text{vol (dL) urine 24h} \times f^*$$

f* = dilution factor

Conversion Factor:

mmol/L = 0,4114 x mg/dL

mmol/24h = 0,04114 x mg/24h

0,5 mmol/L = 1,0 mEq/L = 1,22 mg/dL = 12,2 mg/L

Quality control

Control sera are recommended for the qualification of the reagents and to monitor the performance of assay procedures. Next to legal requirements, we recommend to perform Quality Control on a daily basis and after each calibration.

Use Biochemistry Normal and Pathological Controls (HBC01, HBC02). If other controls (not manufactured by Cypress) are used, they have to be validated by the user as they can vary. Prepare and measure these controls the same as samples. Measure at least one replicate per control.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Do not continue testing as the results will be invalid. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

Reference values

Serum or plasma	1,60 - 2,50 mg/dL (0,66 - 1,03 mmol/L)
Urine	24 - 244 mg/24h (0,99 - 10,04 mmol/24h)

These values are for orientation purpose. Each laboratory should establish its own reference range.

Performance characteristics

Measuring range: from 0,05 mg/dL (detection limit) to 6,6 mg/dL (linearity limit). If the obtained results are greater than 6,6 mg/dL, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

Precision:

	intra-assay (n=20)		inter-assay (n=20)	
	Mean (mg/dL)	SD	Mean (mg/dL)	SD
Mean (mg/dL)	2,13	3,74	2,09	3,72
SD	0,06	0,08	0,06	0,15
CV (%)	2,80	2,26	2,95	4,10

Sensitivity: 1 mg/dL = 0,0982 AU

Accuracy: Results obtained using CYPRESS DIAGNOSTICS reagents did not show systematic differences when compared with other commercial reagents. The results of the performance characteristics depend on the analyzer used.

Interferences

Hemolysis and anticoagulants other than heparin. No interference of hemoglobin up to 22 mg/dL. High values of albumin (> 4,9 g/dL) will interfere. A list of drugs and other interfering substances with magnesium determination has been reported by Young et al.



Notes

1. For best use of this kit on a Cypress Diagnostics analyzer, we kindly advise to follow the application sheets of the respective analyzer. Please log in to our website (www.diagnostics.be) as a registered user to download the latest application sheets, which are located under the section of the corresponding analyzer. Compatible Cypress analyzers: CYANSmart, CYANStart, CYANExpert 130, CYANVision
2. In case other instruments (not manufactured by Cypress Diagnostics) are used, the laboratory is responsible to validate the reagents in this kit on those analyzers before testing patient samples.
3. For this kit, application sheets for the following Mindray analyzers are available (see website): BS-120, BS-200, BS-200E
4. Calibration with the aqueous standard may cause a systematic error in automatic procedures. In this case, it is recommended to use a serum based Biochemistry calibrator (HBC03).
5. Interference by calcium is counteracted by the use of EGTA.
6. It is recommended to use disposable material. If glassware is used, the material should be scrupulously cleaned with H_2SO_4 - $K_2Cr_2O_7$ solution and then thoroughly rinsed with distilled water.
7. Use clean disposable pipette tips for its dispensation.

Bibliography

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5. Tietz N W et al. Clinical Guide to Laboratory tests, 3rd ed AACC 1995.
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Notice: Any serious incident that has occurred in relation to the device shall be reported to Cypress Diagnostics and the competent authority of the Member State in which the user and/or patient is established.

2022-04, Rev. 5.0

