MAGNESIUM
Instruction for use

Ref.: 50

Intended use . End point reaction system for Magnesium determination in serum, urine and cerebrospinal fluid samples.

Professional Use.

[For in vitro diagnostic use.]

Test principle . Magnesium ions react with Magon Sulfonate (Blue color) in alkaline solution yielding a pink complex that is proportional to magnesium ions amount in sample. The color of standard and test tubes is a mixture of blue and pink.

Magnon + Magnesium ⟶ Magon-magnesium complex

Summary . The Magnesium system Labtest, extremely simple and fast, allows that in few minutes an effective differential diagnostic may be performed among hypocalcemia and hypomagnesemia. The small amount of sample required turns it to be the preferred method in pediatry.

The methodology is easily applied to most automated and semi-automated equipments which are able to measure an end point reaction absorbance in a range of 500 and 540 nm.

Methodology . Labtest.

Reagents

1. R 1 - Buffer - Store at 15 - 25 ºC.
Contain Buffer 400 mmol/L, pH 11.5; Potassium carbonate 153 mmol/L and sodium azide 15.4 mmol/L.

2. R 2 - Magon Sulfonate - Store at 15 - 25 ºC.
Contain magon sulfonate 0.1 g/L.

3. CAL - Standard 2.0 mg/dL - Store at 15 - 25 ºC.
After handling it is suggested to store well sealed to avoid evaporation.

Unopened reagents, when stored at indicated temperature, are stable up to expiration date shown on the label. During handling, the reagents are subject to chemical and microbial contaminations that may lead to reduced stability.

Precautions and warnings

Ionic detergent for cleaning the material is a contamination source of magnesium ions.

All stored glass may retain residues that lead to a false increased results.

The usual security cares should be applied on the reagent handling.

Working reagent is an irritant for the eyes, skin and respiratory system. Inhalation must be avoided and in case of eye and skin contacts flush with a large volume of water and seek medical assistance.

The buffer contain sodium azide as preservative. Avoid ingestion. In case of eyes contact, immediately flush eyes with plenty of water and get medical assistance.

Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide accumulation.

To dispose of reagents and biological material we suggest the application of local, state or federal environmental protection standards.

Materials required not provided

1. Photometer capable of measuring absorbance at 500 - 540 nm.
2. Pipettes to measure reagents and samples.
3. Timer

Sample

Use serum or plasma (Heparin), urine and cerebrospinal fluid. Magnesium is reportedly stable in serum for about 5 days at 15 - 25 ºC and 2 weeks at 2 - 8 ºC.

Citrated, oxalate, fluoridated or EDTA plasma provide falsely diminished results.

Hemolytic samples provide false increased results due to magnesium release from red cells. This interference can not be corrected by the sample blank because it is not only a photometric interference.

The 24-hour urine sample should be collected into a bottle containing 50% HCl 10 mL to avoid magnesium and calcium precipitation.

A Standard Operating Procedure (POP) should be created to establish appropriate procedures for sample collection, preparation and storage. We emphasize that the errors due to the sample may be much larger than the errors that occurred during the analytical procedure.

As no known test method assurance that human blood samples will not transmit infectious diseases, they all should be considered potentially infectious. Therefore, when handling them, biosafety standards must be followed.

Interference

Bilirubin up to 8 mg/dL and triglycerides up to 250 mg/dL do not interfere significantly.

Labtest

Bilirubin values ranging from 8 and 32 mg/dL and triglycerides ranging from 250 and 3500 mg/dL provide positive interferences that may be minimized by the following correction:

Minimization of interferences . Add 0.02 mL of 10% EDTA (Hemstab Ref. 30) to 0.2 mL of the sample. Wait 5 minutes. Mix 2.0 mL of Working Reagent to 0.02 mL of the EDTA treated sample and measure the absorbance at 505 nm against the Working Reagent. Subtract the obtained absorbance from the test absorbance and calculate the result.

Preparing the working reagent . See notes 1 and 2.

In an amber plastic bottle, mix equal volumes of Buffer (Nº 1) and Magon Sulfonate (Nº 2) according to tests number. The Working Reagent is stable 2 days at 15 - 25 ºC.

Atmospheric CO2 alters significantly the stability of the buffer (Nº 1) and working reagent, if kept in open bottles. The loss of stability is influenced by allowing the contact among reagent and environmental conditions (air). It is suggested to add into bottles the volume of reagent enough to run the current samples in few hours. In case of remaining reagent into bottles, use the information from the Quality Control as indicator for performing a new calibration.

Procedure

See notes 1 and 2.

The material used in the procedure must be magnesium contamination free in order to avoid getting incorrect results.

Urine: homogenize the 24 hours urine and adjust the pH at 1.0 with 50 % HCl if necessary. Take 5,0 mL and warm up to 56 ºC during 15 minutes. Mix well and dilute the urine 1:5 (1.0 mL urine + 4.0 mL distilled or deionized water). Multiply the result by the dilution factor 5.

Set up three tubes and proceed as follows:

	Blank	Unknown	Standard
Working Reagent	2.0 mL	2.0 mL	2.0 mL
Sample	----	0.02 mL	----
Standard (n° 3)	----	----	0.02 mL

Mix and wait 2 minutes and determine the absorbance of the Unknown and Standard against Blank at 505 nm or green filter (500 - 540 nm), hitting zero with Blank. The color is stable during 30 minutes.
The suggested procedure for the measurement is suitable for photometers whose minimum solution volume for reading is ≤2.0 mL. The volume adjustment must be checked for the photometer used. Sample and reagent volumes may be proportionally modified without impairing the performance of the test while keeping the calculations unchanged. In case of volume reduction it is essential to observe the minimum volume required for the photometric reading. Sample volumes less than 0.01 mL are critical for manual applications and should be used with caution because they increase the imprecision of the measurement.

Calculations

$$\text{Magnesium (mg/dL)} = \frac{\text{Atest}}{\text{Astandard}} \times 2$$

Test Absorbance = 0.250
Standard Absorbance = 0.200

$$\text{Magnesium (mg/dL)} = \frac{0.250}{0.200} \times 2 = 2.5$$

Due the great reproductive results of the assays system, it is possible to use the factor method:

$$\text{Calibration factor} = \frac{2}{\text{Astandard}}$$

Magnesium (mg/dL) = Atest x Factor

Example

$$\text{Calibration Factor} = \frac{2}{0.200} = 10$$

Magnesium (mg/dL) 0.250 x 10 = 2.5

$$\text{Urine (mg/24 hours)} = \frac{\text{mg/dL x 24 hours (mL)}}{100}$$

Calibration

The Standard is traceable to Standard Reference Material (SRM) 929 of the National Institute of Standards and Technology (NIST).

Manual calibrations
Perform a new calibration after reagent lot change or when the internal quality control indicates.

Automatic Systems
Blank of reagents: water or Sodium Chloride solution 150 mmol/L (0,85%);
Standards: Calibra Series (Labtest calibrator for automated systems).

Calibration frequency
Two or three point calibration after reagent lot change;
Two or three point calibration when the internal quality control indicates.

Quality control . For quality control use Qualitrol H Level 1 and Qualitrol H Level 2 or other suitable control material. The limits and control interval must be adapted to the laboratory requirements. Each laboratory should establish corrective measures to be taken if values fall outside the control limits.

Linearity

The linear measurement result is up to 4.5 mg/dL. For larger values dilute the sample with distilled or deionized water and repeat the measurement. Multiply the result obtained by the appropriate dilution factor.

Labtest

Internal quality control . The testing center must keep an internal quality control program that clearly defines all applicable regulations, objectives, procedures, and criteria for quality specifications and tolerance limits, corrective actions and registration of activities. Control materials should be used to assess imprecision and calibration deviations. It is recommended to use a system of control rules to verify the stability of the measuring system[5].

It is suggested to use the stabilized preparations of the Qualitrol - Labtest Line for internal quality control in clinical chemistry trials.

Expected values[6] . These intervals should be used for guidance only. It is recommended that each laboratory establishes its own reference range in the population served.

All ages
Serum . 1.58 - 2.56 mg/dL

Cerebrospinal fluid . 2.5 - 3.5 mg/dL

Urine . 48 - 152 mg/24 hours (variable with the feed).

Conversion . Conventional unit (mg/dL) x 0.41 = SI unit (mmol/L).

Performance characteristics[7]

Accuracy . In two samples with magnesium concentrations of 1.8 and 2.0 mg/dL were added different quantities of the analyte. Subsequent analyses provided recoveries ranging from 93 to 105%. The mean proportional systematic error at 2.0 mg/dL decision level was 0.02 mg/dL or 1%.

Method comparison . The proposed method was compared with a similar method using 40 samples ranging from 0.81 to 3.2 mg/dL. The comparisons yielded a correlation coefficient of 0.989 and regression equation was y = 1.006x - 0.031. The mean total systematic error (proportional and constant) at 2.0 mg/dL decision level was 0.019 mg/dL or 0.95%. As the samples were selected randomly in outpatient and inpatient patients, it can be inferred that the method has an adequate methodological specificity.

Imprecision - Within Run

	N	Mean (mg/dL)	SD (mg/dL)	(%) CV
Sample 1	20	1.5	0.02	1.0
Sample 2	20	3.1	0.04	1.3

Imprecision - Run-to-Run

	N	Mean (mg/dL)	SD (mg/dL)	(%) CV
Sample 1	20	1.5	0.04	3.0
Sample 2	20	3.0	0.06	2.0

Methodological sensitivity . A non-magnesium-containing protein sample was used to calculate the detection limit of the assay and a value of 0.032 mg/dL was found, equivalent to the mean of 20 assays plus two standard deviations. Using the absorbance of the standard as a parameter it was found that the limit of photometric detection is 0.01 mg/dL, corresponding to an absorbance of 0.001.

Effects of matrix dilution . Two samples with values equal to 4.2 and 4.4 mg/dL were used to evaluate the system response in the matrix dilutions with 150 mmol/L NaCl (0.85%). Using dilution factors ranging from 2 to 4, recoveries between 95 and 101% were found.

Notes

1. The material cleaning and drying are fundamental factors to the reagent stability and to obtain correct results.

2. The clinical laboratory aims to provide accurate and accurate results. The use of water of inadequate quality is a potential cause of analytical errors. The deionized or distilled water used in the laboratory should have the right quality for each application. Thus, to prepare reagents, use in the measurements and for use in the final rinse of the glassware must have resistivity ≥1 megohm.cm or conductivity ≤1 microsiemens/cm and concentration of silicates <0.1 mg/L. When the deionizing column is saturated, the production of alkaline water with the release of several ions, silicates and substances with great oxidation or reduction power, which deteriorates the reagents in a few days or even hours, results in unpredictable results. Thus, it is essential to establish a water quality control program.

3. It is suggested to consult "www.fxol.org" in order to review physiopathological source and drugs interference in results and methodology.

References

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4. Tonks DB. Quality Control in Clinical Laboratories, Warner-Chilcott Laboratories, Diagnostic Reagents Division, Scarborough, Canada, 1972.
5. Westgard JO, Barry PL, Hunt MR, Groth T. Clin Chem. 1981, 27:493-501.
6. Tietz. Textbook of Clinical Chemistry, Buritis CA.: Ashwood ER. Eds, 2ª edição, Philadelphia: WB. Saunders Co, 1994.
7. Labtest: data on file.

Presentation

Product	Reference	Content
Magnesium	50-2/36	R 1 2 X 18 mL R 2 2 X 18 mL CAL 1 X 3 mL
	50-1/200	R 1 1 X 100 mL R 2 1 X 100 mL CAL 1 X 3 mL
	50-2/200	R 1 2 X 100 mL R 2 2 X 100 mL CAL 1 X 3 mL

Applications for **automatic and semi-automatic systems** are available.

The number of tests in automatic applications **depends on the programming parameters.**

Customer information

[Warranty conditions]

Labtest Diagnóstica warrants the performance of this product under the specifications until the expiration date shown in the label since the application procedures and storage conditions, indicated on the label and in this insert, have been followed correctly.

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Símbolos utilizados com produtos diagnósticos in vitro

Símbolos usados con productos diagnósticos in vitro . Symbols used with ivd devices

Conteúdo suficiente para < n > testes Contenido suficiente para < n > tests Contains sufficient for < n > tests	**Consultar instruções de uso** Consultar instrucciones de uso Consult instructions for use	**Controle** Control Control	**Tóxico** Tóxico Poison
Data limite de utilização (aaaa-mm-dd ou mm/aaaa) Estable hasta (aaaa-mm-dd o mm/aaaa) Use by (yyyy-mm-dd or mm/yyyy)	**Número do catálogo** Número de catálogo Catalog Number	**Controle negativo** Control negativo Negative control	**Reagente** Reactivo Reagent
Material Calibrador Material Calibrador Calibrator Material	**Adições ou alterações significativas** Cambios o suplementos significativos Significant additions or changes	**Controle positivo** Control positivo Positive control	**Fabricado por** Elaborado por Manufactured by
Material Calibrador Material Calibrador Calibrator Material	**Produto diagnóstico in vitro** Dispositivo de diagnóstico in vitro In vitro diagnostic device	**Controle** Control Control	**Número do lote** Denominación de lote Batch code
Limite de temperatura (conservar a) Temperatura limite (conservar a) Temperature limitation (store at)	**Liofilizado** Liofilizado Lyophilized	**Risco biológico** Riesgo biológico Biological risk	**Período após abertura** Período post-abertura Period after-opening
Representante Autorizado na Comunidade Europeia Representante autorizado en la Comunidad Europea Authorized Representative in the European Community	**Corrosivo** Corrosivo Corrosive	**Marca CE** Marcado CE CE Mark	**Uso veterinário** Uso veterinario Veterinary use
Instalar até Instalar hasta Install before			

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