MEDICA

REF 10220-4 4 x 29mL/9 mL

MAGNESIUM (Mg)

Wedges each contain a useable volume of 29 mL of reagent and 9 mL of R2 acid cleaning solution.

INTENDED USE

The EasyRA magnesium reagent is intended for the quantitative measurement of Magnesium (Mg) in human serum and plasma, using the MEDICA "EasyRA Chemistry Analyzer" in clinical laboratories. Magnesium measurements are used in the diagnosis and treatment of: Hypomagnesaemia occurring during renal failure, acute diabetic acidosis, and dehydration or in Addison's disease. Hypomagnesaemia observed in cases of chronic alcoholism, malabsorption, acute pancreatitis and kidney disorders.
For *in-vitro* diagnostic use only.

SUMMARY AND EXPLANATION

Almost 50% of the Magnesium (Mg) in the human body is found in the bones and associated with calcium and phosphorus [1].
The amount of magnesium ingested and absorbed through the intestines is inversely proportional to the total magnesium intake, which is controlled by the kidneys. The kidneys reabsorb excess magnesium when intake is low and excretes excess when the intake is high.[2]
Magnesium is a required cofactor in the metabolism of carbohydrate, lipids and proteins. An increase in the serum Mg level in the serum can occur during renal failure, acute diabetic acidosis, and dehydration or in Addison's disease and can lead to impaired respiration, coma and cardiac arrest if uncorrected. Low levels of Mg may be observed in cases of chronic alcoholism, malabsorption, and acute pancreatitis and kidney disorders such as glomerulonephritis and may lead to tremors, muscle irritability, increased blood pressure and heart rate if uncorrected.

PRINCIPLE OF THE PROCEDURE

This assay method employs the binding of xylidyl blue-1 dye to magnesium to form the Mg-xylidyl blue complex, according to the following equation:

Mg^{++} + Xylidyl blue-1 $\longrightarrow$ Mg-xylidyl blue complex (red)

The increase of absorbance of the red complex at 520 nm is directly proportional to the concentration of magnesium in the sample. The absorbance decrease at 600 nm is directly proportional to the Magnesium in the serum combining with the Xylidyl blue-1 dye.

REAGENTS

Buffer, pH 11.1 at 25ºC	
Xylidyl blue-1	0.14 mmol/L
Ethylenebis (oxyethylenenitrilo) tetra acetic acid (EGTA)	0.1 mmol/L
Surfactant and preservative.	

The R2 segment of the wedge contains acid to clean the probe prior to performing the Magnesium test:

Hydrochloric Acid	50mmol/L
Surfactant	

Precautions

1. Good laboratory safety practices should be followed when handling any laboratory reagent. (*NCCLS,* GP17-A2).
2. The reagent contains less than 0.1% of sodium azide, which may react with lead and copper plumbing to form highly explosive metal azides. Refer to the Safety Data Sheet for risk, hazard and safety information.
3. As with any diagnostic test procedure, results should be interpreted considering all other test results and the clinical status of the patient.
4. Do not use washed cuvettes.

Instructions for Reagent Handling, Storage and Stability

The reagent is ready to use as supplied. Unopened reagent is stable until the expiration date listed on the label if stored at 2º-8ºC. The reagent is stable on-board in the refrigerated reagent area of the Medica EasyRA Chemistry Analyzer for the number of days programmed on the RFID chip on the reagent wedge if the reagent is recapped and removed at the end of the day and stored overnight at 2º-8ºC. Do not use the reagent if it is turbid or cloudy or if it fails to recover known serum control values.

SPECIMEN COLLECTION AND STORAGE / STABILITY

Clear unhemolyzed serum and plasma should be used. Lithium Heparin coated tubes may be used for plasma collection. Centrifuge and remove the serum as soon as possible after collection. Serum Magnesium is stable for 5 days at 2-8ºC. [2]

PROCEDURE

Materials Provided
Medica Mg Reagent Wedge, REF 10220

Additional materials required
Medica EasyCal Chemistry, REF 10651
Medica EasyQC Chemistry/Electrolytes – Level A, REF 10793
Medica EasyQC Chemistry/Electrolytes – Level B, REF 10794
Medica Precision Test Dye Wedge, REF 10764
Medica Cleaner Wedge – Chemistry & ISE, REF 10660 *or*
Medica Cleaner Wedge – Chemistry, REF 10661

Instructions for Use
The reagent is ready to use as supplied. Remove the cap and place the reagent in the Medica EasyRA Chemistry Analyzer reagent tray located in the reagent area. The on-board stability (17 days maximum) is programmed on the RFID chip on the reagent wedge.

Note: Check the inside of the necks of the wedge for foam after removing the caps and placing the wedge on the analyzer. If there is foam, remove it with a swab or a disposable pipette before performing the test. Use separate swabs or disposable pipettes for R1 and R2.

Calibration
Medica EasyCal Chemistry, REF 10651 is recommended for the calibration of the assay. The calibration interval (3 days maximum) is programmed on the RFID chip on the reagent wedge. Recalibration is required whenever there is a change in reagent lot number, a new wedge of the same lot number is placed in the reagent chamber, or if a shift in quality control values occurs.

Quality Control
It is recommended that two levels of human serum based controls (normal and abnormal) be run with the assay at least once every 8 hours and with each reagent lot change. Failure to obtain the proper range of values in the assay of control material may indicate reagent deterioration, instrument malfunction, or procedural errors. The laboratory should also follow local, state, and federal quality control guidelines when using quality control materials.

RESULTS
After completion of the assay, the Medica EasyRA Chemistry Analyzer calculates the Magnesium concentration from the ratio of the absorbance of the unknown sample to the absorbance of the calibrator, multiplied by the calibrator value.

$$\text{Mg (mg/dL)} = \frac{[(A_U - A_{Blk})_{520} - (A_U - A_{Blk})_{600}]}{[(A_C - A_{Blk})_{520} - (A_C - A_{Blk})_{600}]} \times \text{Cal Value}$$

Where A_U and A_C are the absorbance values of unknown and calibrator, respectively; A_{Blk} is the absorbance of the reagent blank; and "Cal Value" is the concentration of Magnesium in the calibrator (mg/dL).

Expected Values [4]
The reference range for Mg in serum is as follows:

Normal: 1.6 - 2.6 mg/dL

These values are only suggested guidelines. It is recommended that each laboratory establish its own range of expected values, since differences exist among instruments, laboratories and local populations.

Procedural Limitations (e.g. if sample is above assay range)
Avoid using heavily hemolyzed serum or plasma samples.

The Medica EasyRA Chemistry Analyzer flags any result above 6.1 mg/dL as Linearity High "LH". If the "Re-run" icon is selected by the operator, the sample may be re-tested using one half (1/2) the sample volume. The retest results are calculated to reflect the use of the smaller sample volume. This will effectively extend the reportable range of the Mg test to 12.2 mg/dL.

PERFORMANCE CHARACTERISTICS [5]

Reportable Range
The reportable range is 0.04 to 6.1 mg/dL. Extended range is 0.04 to 12.2 mg/dL when half of the sample is used (1:1 dilution).

Inaccuracy/ Correlation (NCCLS, EP9-A2)
The following table lists the data obtained in a comparison of the Medica Reagent for Mg (y) on the Medica EasyRA Chemistry Analyzer to the performance of a similar Mg reagent (x) run on the Medica EasyRA Chemistry Analyzer. The data shown below represents single determinations obtained on the Medica EasyRA Chemistry Analyzer vs. the average of 2 replicate values obtained on the Medica EasyRA Chemistry Analyzer.

Number of samples	44	Range of Samples	0.05 to 5.82 mg/dL
Slope	1.0738	y Intercept	-0.1327
Correlation Coefficient	0.9985	Regression Equation	Y = 1.0738*X - 0.1327

The following table lists the data obtained in a comparison of matched serum (x) and Li-Heparinized plasma (y) samples using the Medica Reagent for Mg on the Medica EasyRA Chemistry Analyzer. The data below represents a single plasma determination vs. the average of two replicate serum values.

Number of Samples	72	Range of Samples	0.14 to 6.07 mg/dL
Slope	1.0141	y Intercept	-0.0474
Correlation	0.9973	Regression Equation	Y = 1.0141*X – 0.0474

Imprecision (NCCLS, EP5-A2)
Duplicate measurements of each of three levels of QC material were tested twice a day for 20 days. Both within-run precision and total precision were determined from these data.

Within run imprecision:

QC Level mg/dL	Within Run SD mg/dL	Within Run CV %
4.80	0.06	1.2
1.82	0.02	1.2
1.06	0.01	1.2

Total Imprecision:

QC Level mg/dL	Total Imprecision SD mg/dL	Total Imprecision CV %
4.80	0.10	2.0
1.82	0.04	2.0
1.06	0.02	1.9

Linearity (NCCLS, EP6-A)
Linear from 0.04 to 6.1 mg/dL, based on the linear regression Y = 1.0088*X – 0.1519.

Limit of Blank (LOB):	0.03 mg/dL	(NCCLS, EP17-A)
Limit of Detection (LOD):	0.04 mg/dL	(NCCLS, EP17-A)

Interfering Substances (NCCLS, EP7-A)
Less than 10% interference was classified as “no significant interference”.
There is significant interference at hemoglobin levels above 400 mg/dL
No significant interference was found in levels up to 38 mg/dL of bilirubin.
No significant interference was found at levels of up to 2200 mg/dL of triglycerides (using Intralipid*).

**Intralipid is a registered trademark of Pharmacia AB, Clayton, NC*.

Young provides a list of drugs and other substances that interfere with clinical chemistry tests [6,7].

REFERENCES

1. Henry JB, ed. *Clinical Diagnosis and Management by Laboratory Methods.* Philadelphia, PA. WB Saunders and Company; 1984: 157-158.
2. Tietz NW. Editor, *Fundamentals of Clinical Chemistry*. 2nd ed. WB Saunders and Co., Philadelphia, PA, 1976: 971-974.
4. Tietz NW. Editor, *Clinical Guide to Laboratory Tests* WB Saunders and Co., Philadelphia, PA, (1983) 338.
5. Data on file at Medica
6. Young DS. *Effects of Drugs on Clinical Laboratory Tests* 4th ed. Washington, DC: AACC Press; 1995.
7. Young DS. *Effects of Preanalytical Variables on Clinical Laboratory Tests*. 2nd ed. Washington, DC. AACC Press; 1997.

EasyRA Assay Parameters (Mg)

Primary Wavelength (nm)	520
Secondary Wavelength (nm)	600
Reaction Type	Endpoint (2)
Reaction Direction	Increase
Reagent Blank	Yes (with each calibration)
Sample Blank	No
Reaction Time	2.0 min
Calibration interval (maximum)	3 days
Reagent on-board stability	17 days

Serum

Sample volume (µl)	2.0
Diluent volume (µl)	20
Reagent volume (µl)	180
Decimal Places (default values)	2
Units (default values)	mg/dL
Dilution Factor to extend measuring range	1:1
Linearity	0.04 to 6.1 mg/dL

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