diatron

MAGNESIUM

For use on Diatron Pictus® series analyzers
Method: Xylidyl blue
Product code: 1419-0252, 1419-0250
Package: 8 x 21 ml, 8 x 9 ml
Store at: 2° – 8°C
For *in vitro* use only

INTENDED USE
Ready to use reagent for the quantitative determination of magnesium in human serum or urine specifically for use with Diatron Pictus® series analyzers. For *in vitro* diagnostic use only.

CLINICAL SIGNIFICANCE
The concentration of magnesium in serum increases in dehydration, chronic or acute renal insufficiency, uncontrolled diabetes mellitus (rare), adrenocortical insufficiency, Addison's disease, tissue trauma, hypothyroidism, lupus erythematosus, multiple myeloma.
Decrease is observed in inadequate intake or impaired absorption of magnesium (e.g. malabsorption syndrome, Kwashiorkor syndrome, diet low in proteins and calories), acute pancreatitis, hypoparathyroidism, chronic alcoholism, delirium tremens, disorders associated with increased magnesium requirements and inadequate replacement of body fluids, chronic glomerulonephritis, hyperaldosteronism, diabetic acidosis, excessive lactation, inappropriate secretion of ADH, pregnancy (2nd and 3rd trimester), idiopathic hypomagnesemia, renal conservation of magnesium. Tetany may occur at magnesium concentrations 0.36 – 1.2 mg/dl at normal pH and normal calcium concentrations.

METHOD PRINCIPLE
The Xylidil Blue colorimetric method is applied. Magnesium in alkaline environment forms a colored complex with the xylidyl blue. The absorbance at 505/750 nm is proportional to the concentration of magnesium in the sample. Glycoletherdiamine-N,N,N',N',-tetraacetic acid (GEDTA) is added for chelation of calcium so it will not interfere in the reaction.

METHOD LIMITATIONS
Refer to the book "Effects of Preanalytical Variables on Clinical Laboratory Tests" for possible interference of other pharmaceutical agents in this particular test. Interference of other agents is described in the "Clinical Guide to Laboratory Tests".
The reagent is designed especially for use with the Diatron Pictus® series of chemistry analyzers. For chemistry protocols and further information please contact the customer support unit at Diatron.

REAGENT COMPOSITION
EGTA: 0.10 mM
Xylidyl blue: 0.18 mM
CAPS: 85 mM
Non reactive ingredients, preservative.

WARNINGS - PRECAUTIONS
- These reagents are designed for in vitro diagnostic use. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory techniques. Avoid inhalation and contact with eyes and skin.
- Samples should be considered as potentially infectious. Handle with special caution.
- This reagent contains sodium azide (NaN_3) ≤ 0.1%. Avoid swallowing and contact of the reagent with skin and mucous membranes.
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON HELLAS (manufacturer) upon request.

REAGENT PREPARATION
The reagents are ready-to-use when placed in the corresponding positions of the analyzer. The vials bear barcodes for automatic recognition by Pictus® series analyzers.

REAGENT DETERIORATION
The reagents should not be used:
- When they do not exhibit the specified linearity or control values lie outside the acceptable range after recalibration.
- When it appears decolorized.
- After prolonged exposure to sunlight or high temperature.

SHELF LIFE
Unopened, the reagents are stable at 2°– 10°C up to the expiry date stated on the label. Once opened, they remain stable for 7 days when stored in the cooled reagent tray of the Pictus® series analyzers.

SAMPLE
Specimens of fresh, non-hemolyzed serum or heparinized plasma should be used. Do not use other anticoagulants. Serum samples are stable for 7 days at room temperature. Urine samples are stable at room temperature when acidified with 6N HCl (pH 1). If there is precipitate formation, shake, acidify and warm the sample at 60°C. Avoid repeated freezing-thawing of the samples.

CALIBRATION
Diatron provides MEDI-CAL (1578-0891) for serum calibration, and the MEDI-CAL U (1579-0185) for urine calibration. Calibrate the assay every 3 days when used on Pictus® series analyzers. Calibration should also be repeated after major maintenance is performed on the analyzer, after a critical part is replaced, or when a significant shift in control values occurs.

QUALITY CONTROL
Diatron provides Clinical Chemistry Control Level 1 & 2 (1578-0901-12 & 1578-0902-12 respectively) for serum quality control, and the MEDITROL-U 1,2 (1579-0181) or Urine Control Normal code: 1778-0181, Abnormal code: 1778-0182) for urine quality control.
Control recovery should lie within the acceptable range. Results outside the acceptable range even after recalibration could be due to reagent deterioration, unsuitable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

MATERIALS REQUIRED BUT NOT SUPPLIED WITH THE KIT
- Magnesium calibrator
- Quality control materials.
- Diatron Pictus® P400/P700/P500
- Common laboratory equipment

REFERENCE INTERVALS
Serum, plasma: 1.6 – 2.3 mg/dl
Urine: 24 – 255 mg/24h
Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practices.

WASTE DISPOSAL
This product contains sodium azide (NaN_3), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build up in the drain.

SPECIFIC PERFORMANCE CHARACTERISTICS
The following values are representative of the reagent performance on Diatron Pictus® series analyzers. The reagent performance has been evaluated on other types of analyzers, covering all requirements of the 98/79 IVD Directive. A list of analyzers with the corresponding performance characteristics is available in the special leaflet accompanying the insert. The results taken in your laboratory may differ from these values.

	Pictus® P400	Pictus® P700/P500
Linearity	Serum: up to 7 mg/dL Urine: up to 15.0 mg/dL	Serum: up to 7 mg/dL Urine: up to 22 mg/dL
Lowest detection limit	Serum: 0.34 mg/dL Urine: 0.3 mg/dL	Serum: 0.13 mg/dL Urine: 0.37 mg/dL

The lowest detection limit (LDL) is defined as the lowest concentration of analyte that is distinguishable from zero. A sample free of analyte is assayed 20 times within the assay and the LDL is calculated as the absolute mean plus three standard deviations.
Precision: Precision is estimated on two concentration levels of analyte according to CLSI protocol EP 5T (20 consecutive days, 2 runs per day, 2 repeats per run).

Serum	Pictus® P400			Pictus® P700/P500		
	Level (mg/dL)	Within Run CV%	Total CV%	Level (mg/dL)	Within Run CV%	Total CV%
	1.72	2.74	3.39	1.76	3.09	4.71
	3.91	2.34	3.04	4.19	2.65	3.75

Interferences: Criterion: recovery within ±20% from target value

Serum:	Pictus® P400	Pictus® P700/P500
Lipemic	No interference up to 1000 mg/dL Intralipid®	No interference up to 300 mg/dL Intralipid®
Heamoglobin	No interference up to 500 mg/dL	No interference up to 500 mg/dL
Non conj. Bilirubin	No interference up to 20 mg/dL	No interference up to 20 mg/dL
Conj. Bilirubin	No interference up to 20 mg/dL	No interference up to 20 mg/dL
Ascorbate	No interference up to 3 mg/dL	No interference up to 3 mg/dL
Urine:	**Pictus® P400**	**Pictus® P700/P500**
Heamoglobin	No interference up to 500 mg/dL	No interference up to 400 mg/dL
Conj. Bilirubin	No interference up to 50 mg/dL	No interference up to 20 mg/dL
Non conj. Bilirubin	No interference up to 50 mg/dL	No interference up to 20 mg/dL
Creatinine	No interference up to 300 mg/dL	No interference up to 300 mg/dL
Gentamycin	No interference up to 10 g/L	No interference up to 10 g/L
Urea	No interference up to 50 g/L	No interference up to 50 g/L
Glucose	No interference up to 3 g/L	No interference up to 10 g/L
Ascorbate	No interference up to 5 g/L	No interference up to 5 g/L

Correlation: A comparison was performed between this reagent on a Pictus® series analyzer, and a BECKMAN COULTER AU-series system. The results were as follows:

Pictus® P400
Serum: Y = 0.967X + 0.274 R=0.9288 N=60 Sample range = 1.41 – 2.95 mg/dL
Urine: Y = 0.919X - 0.043 R=0.9974 N=20 Sample range = 0.3 – 12.7 mg/dL
Pictus® P700/P500F
Serum: Y = 0.917X + 0.262 R=0.9728 N=40 Sample range = 0.99 – 3.22 mg/dL
Urine: Y = 0.9163X – 0.6143 R=0.9673 N=40 Sample range = 0.53 – 23.38 mg/dL

BIBLIOGRAPHY

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3. Jacobs, DJ, Demotte, WR, Grady, HJ, Horvath, RJ, Huestis, DW and Kasten, BL, JR, eds. Laboratory Test Handbook. 4th. ed. Ohio, Hudson: Lexi-Comp Inc., 1996.
4. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd. ed. Washington, DC: The American Association for Clinical Chemistry Press, 1997.
5. Mann, CK, Yoe, JH. Anal. Chem. 1956; 28: 202-205.
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SYMBOLS
Temperature Limits (L/H)
Manufacturer
Read the Instructions
REF Catalog Number (ISO 15223 / rev. EN980)
LOT Batch Code (ISO 15223 / rev. EN980)
IVD For in vitro use (ISO 15223 / rev. EN980)
Date of Expiry (ISO 15223 / rev. EN980)

CE IVD

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