diatron

MAGNESIUM

2°C – 8°C

Specifically for use with Diatron PICTUS® 700 and PICTUS® 500 Analyzers

REF 1419-0250 **Packaging:** 8 x 9 mL

Σ 296

INTENDED USE
Reagents for In Vitro quantitative automated determination of Magnesium in human serum or urine in the general patient population. Measurements of Magnesium are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid for screening, diagnosis and management of several comorbidities involving marked changes in magnesium concentration.

This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers.
For in vitro diagnostic use only by trained laboratory professionals.

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". This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers. For additional information please contact customer support at Diatron or Medicon.

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.
- Any serious incident that may occur in relation to this device must be reported by the user to the manufacturer and the competent authority of the country in which the user and/or the patient is established!
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON upon request.

⚠ **PREPARATION**
The reagents are ready-to-use when placed in the corresponding positions of the analyzer. The vials bear barcodes for automatic recognition by Diatron Pictus® P700 / P500 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°– 8°C up to the expiry date stated on the label. Once opened, they remain stable for 1 week when stored in the cooled reagent tray of the Diatron Pictus® P700 or P500 analyzers.

⚠ **SAMPLE** Serum and 24-hour urine may be used as specimen.
Serum: Use established Good Laboratory Practices for sampling (avoid tourniquet), transport and separation from blood cells. Use only metal-free materials for sampling. Do not use hemolyzed, contaminated or turbid sample specimens. Centrifuge sample as soon as possible and store properly if analysis cannot take place right after sample separation. Magnesium in serum is stable for up to 7 days at 2 - 8°C.
Urine: 24-hour urine may be used as specimen. Use established Good Laboratory Practices for sampling and transport. Clinically relevant results have not been validated with random urine samples. Patients don't need to have fasted for sample gathering. During urine collection, avoid sample contamination by contact with hands or other objects, because it may lead to false increase of albumin levels in the sample. Keep collection container at 2 – 8°C during sample collection. Analyze sample as soon as possible (within 1 hour) from last urination.

CALIBRATION Diatron offers MEDICON MEDI-CAL (1578-0891) traceable to SRM 909b NIST for serum calibration. Calibrate the assay every 3 days when used on Diatron Pictus® P700 or P500 analyzers. Perform a Reagent Blank measurement every 3 days. 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. Urine Applications are pre-programmed on the analyzer to automatically acquire a calibration factor after every successful serum calibration.

QUALITY CONTROL Diatron offers MEDICON Clinical Chemistry Control Level 1 & 2 (1578-0901-12 & 1578-0902-12 respectively) for serum 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 PROVIDED WITH THE KIT
- Magnesium Calibrator
- Quality control materials
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS
Serum: 1.6 – 2.3 mg/dl
Urine: 73 – 122 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® P700 or P500 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.
Linearity up to 7 mg/dL
Lowest detection limit 0.13 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).

Pictus® P700 and P500	
Mean (mg/dL)	**%CV**
1.30	2.40
3.30	4.90
Mean (mg/dL)	**TOTAL %CV**
1.30	8.80
3.30	6.40

INTERFERENCES - Criterion: recovery within ±10% from target value

	(Insignificant up to)
Triglycerides	900 mg/dL
Hemoglobin	500 g/dL
Bilirubin	20 mg/dL
Conj. Bilirubin	20 mg/dL
Ascorbic acid	3 mg/dL

Correlation: A comparison was performed between this reagent on a Diatron Pictus® P700 and P500 analyzer and another commercially available product. The results were as follows:
Y = 0.917X + 0.262 R=0.9728 N=40 Sample range = 0.99 – 3.22 mg/dL

BIBLIOGRAPHY

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⚠ **LABEL ELEMENTS**

Precautionary Statements (P Phrases)	Hazardous Statements (H Phrases)
P260: Do not breathe dust/ fumes/ gas/ mist/ vapors/ spray.	**H300**: Fatal if swallowed.
P280: Wear protective gloves/protective clothing/eye protection/face protection.	**H302**: Harmful if swallowed.
P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting	**H310**: Fatal in contact with skin.
P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.	**H314**: Causes severe skin burns and eye damage.
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.	**H319**: Causes serious eye irritation.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	**H373**: May cause damage to organs through prolonged or repeated exposure
	H400: Very toxic to aquatic life.
	H410: Very toxic to aquatic life with long lasting effects.
	H411: Toxic to aquatic life with long lasting effects.

SYMBOLS

Manufacturer	IVD *In vitro* diagnostic medical device
Temperature Limit	REF Catalogue Number
Caution	Σ Contains sufficient for <n> tests

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