PHOSPHORUS

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

REF 1419-0212 **Packaging:** 8 x 21 mL Σ 840

INTENDED USE
Reagents for In Vitro quantitative automated determination of Phosphorus in samples of human serum or urine from the general patient population. Measurements of Phosphorus 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 conditions known to cause abnormally high or low levels of phosphorus.

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 phosphorus in serum increases in osteolytic metastatic bone tumors, myelogenous leukemia, sarkoidosis, vitamin D intoxication, renal failure, hypoparathyroidism, pseudohypoparathyroidism, diabetes mellitus with ketosis, acromegaly, malignant hyperpyrexia following anesthesia, pulmonary embolism, portal cirrhosis, lactic acidosis, respiratory acidosis, healing fractures etc.
Phosphorus levels decrease in osteomalacia, steatorrhea, renal tubular acidosis, growth hormone deficiency, acute alcoholism, Gram-negative bacterial septicemia, hypokalemia, familial hypophosphatemic rickets, severe malnutrition, malabsorption, diarrhea, vomiting, nasogastric suction, primary hyperparathyroidism, PTH-producing tumors, familial hypocalciouric hypercalciemia, severe hypercalciemia of any cause, acute gout, respiratory infections, hyperinsulinemia, respiratory infections or alkalosis, osteoblastic metastases of cancer, renal tubular defects, diuretic phase of severe burns.

METHOD PRINCIPLE
The Molybdate UV method is applied. Phosphate reacts with ammonium molybdate in strongly acidic pH, forming a complex. The absorbance of the complex at 340/750 nm is proportional to the phosphorus concentration in the sample.

$7H_3PO_4 + 12(NH_4)_6Mo_7O_{24}\cdot 4H_2O \longrightarrow 7(NH_4)_3[PO_4(MoO_3)_{12}] + 51NH_4^+ + 51HO^- + 33H_2O$

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

H2SO4:	130mM
Ammonium molybdate:	0.28 mM

WARNINGS – PRECAUTIONS
- This reagent is 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 H_2SO_4. 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 reagent is ready-to-use when placed in the corresponding position on the analyzer. The vials bear bar codes for automatic recognition by Diatron Pictus® P700 / P500 analyzers.

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

SHELF LIFE
Unopened, the reagent is stable at 2 – 25°C up to the expiry date stated on the label. After opening it remains stable for 2 months when stored in the cooled reagent tray of the Diatron Pictus® P700 or P500 analyzers.

SAMPLE Serum or 24-hour urine may be used as specimen. Use established Good Laboratory Practices for sampling, transport and separation of serum from blood cells. Do not use hemolyzed, contaminated or turbid sample specimens. Centrifuge sample as soon as possible, since red blood cells contain high concentrations of phosphate esters that may release inorganic phosphorus during storage. and store properly if analysis cannot take place right after sample separation. Inorganic phosphorus is stable in serum for 2 days at room temperature, and at least 30 days at 2 – 8°C. Do not freeze thawed samples.
Urine: 24h specimens should be collected in a bottle that contains 20 – 30 mL HCl 6M, to avoid precipitation of phosphate salts. Urine samples should be diluted in a 1:10 ratio with deionized water. Let sample reach room temperature before testing. NOTE: Large quantities of organic phosphates may be present in urine, which may interfere with the test, if sample is exposed to elevated temperatures during collection. The excretion of phosphorus in urine varies with diet and is practically analogous to phosphorus intake from food. Phosphorus is stable in acidified urine for up to 6 months at 2 – 8°C.

CALIBRATION Diatron offers MEDICON MEDI-CAL (1578-0891) traceable to Medicon Master Lot, for serum calibration. Calibrate the assay when a new lot of reagent is installed. The analyzers will automatically perform a Reagent Blank measurement every 1 month. 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
- Phosphorus calibrator
- Quality control material
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS
Serum: 2.6 – 4.5 mg/dl (adults)
3.6 – 5.9 mg/dl (children 1 – 12 years)
Urine:0.4 – 1.3 g/24h (adults in no special diet)
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.

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 for the CE Mark. 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 **Serum:** up to 12 mg/dL **Urine:** up to 200 mg/dL
Lowest detection limit **Serum:** 0.03 mg/dL **Urine:** 1.94 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			
SERUM		**URINE**	
Level (mg/dL)	**%CV**	**Level (mg/dL)**	**%CV**
4.10	1.80	2.15	25.9
7.10	1.60	1.33	46.0
Level (mg/dL)	**Total %CV**	**Level (mg/dL)**	**Total %CV**
4.10	3.40	2.15	2.67
7.10	2.50	1.33	1.96

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

Serum	(Insignificant up to)	**Urine**	(Insignificant up to)
Hemoglobin	200 g/dL	Bilirubin	20 mg/dL
Bilirubin	20 mg/dL	Ascorbic Acid	5 g/L
Conj. Bilirubin	20 mg/dL	Glucose	10 g/dL
Ascorbic acid	3 mg/dL	Uric Acid	2.5 g/dL
		Creatinine	3 g/dL
		Urea	5 g/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:

Serum: Y = 0.979X + 0.382	R=0.9823	N=40	Sample range = 2.85 – 9.72 mg/dL
Urine: Y = 0.758X + 4.5527	R=0.9969	N=40	Sample range = 14.0 – 116.2 mg/dL

BIBLIOGRAPHY

1. Tietz, NW, ed. Clinical Guide to Laboratory Tests. 3rd. ed. Philadelphia: W.B. Saunders Company Ltd., 1995.
2. Burtis, CA and Ashwood, ER, ed. Tietz Textbook of Clinical Chemistry. 2nd. ed. Philadelphia: W.B. Saunders Company Ltd., 1994.
3. Jacobs, DJ, Demott, WR, Grady, HJ, Horvat, 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.

LABEL ELEMENTS

Precautionary Statements (P Phrases)	Hazardous Statements (H Phrases)
P102: Keep out of reach of children. **P260**: Do not breathe dust/ fume/ gas/ mist/ vapors/ spray. **P280**: Wear protective gloves/protective clothing/eye protection/face protection. **P301+P330+P331**: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting **P303+P361+P353**: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. **P304+P340**: IF INHALED: Remove person to fresh air and keep comfortable for breathing.	**H290**: May be corrosive to metals. **H314**: Causes severe skin burns and eye damage.

SYMBOLS

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

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