ROBONIK®

CE

prietest™ ...Clinical Chemistry Reagents

PHOSPHORUS

In vitro diagnostic test kit, for professional use only

INTENDED USE : Quantitative in vitro determination of activity of phosphorus in serum, plasma or urine on photometric systems.

ORDERING INFORMATION	**Pack Size**	**Cat No.**
	1 X 25 ml	PHO 0125
	1 X 50 ml	PHO 0150

CLINICAL SIGNIFICANCE : The main part of phosphorus of the human body (80 to 85 %) is located in bones. The remaining phosphorus is mainly inorganic phosphate. Usually, there is a relationship between calcium and phosphate in human serum. An increase of one of these components usually leads to a decrease of the other component. An elevation of serum phosphate can occur in vitamin D intoxication, hypoparathyroïdism and renal failure. A decrease of serum phosphate is bound to vitamin D deficiency and hyperparathyroidism.

METHOD :
Photometric, End Point, UV.

PRINCIPLE :

$$\text{Ammonium molybdate} + \text{Sulfuric Acid} \xrightarrow{\text{Phosphorus}} \text{Phosphomolybdate complex}$$

REAGENTS :
COMPONENTS AND CONCENTRATIONS :

Sulphuric Acid	:	210 mmol/l
Ammonium Molybdate	:	0.4 mmol/l
Preservative & Stabilizer		
Standard	:	5 mg/dl (1.62 mmol/L)

STORAGE INSTRUCTIONS AND REAGENT STABILITY :
The reagents are stable up to the end of the indicated date of expiry on the vial label, if stored at 2 to 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

WARNINGS AND PRECAUTIONS :
Take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT :
Please refer to local regulation requirements.

REAGENT PREPARATION :
Reagent and standard are ready-to-use.

MATERIALS REQUIRED BUT NOT PROVIDED :
NaCl solution 9 g/l, General laboratory equipment, Analyser / Photometer, Pipettes etc.

SPECIMEN :
Serum free of hemolysis from fasting patient, Heparinized plasma.
Acidified urines are stable for 6 months.
Plasma and serum are stable at 4°C for 1 week, frozen for several months.
Discard contaminated specimens.

ASSAY PROCEDURE :
Application sheets for automated systems are available on request.

Wavelength	:	Hg 340 nm
Optical Path	:	1 cm
Temperature	:	37°C
Mode	:	End Point

Bring all the contents of the kit to Room Temperature prior to use.
Read absorbance of sample against reagent blank
Label the test tube as blank, standard, sample, control and pipette into respective test tube the reagent, standard, sample, control sample as per the table given below :

	Blank	Standard	Sample / Control
Reagent	1000 µl	1000 µl	1000 µl
Distilled Water	10 µl	—	—
Standard	—	10 µl	—
Sample / Control	—	—	10 µl

Mix and read the absorbance (A) after a 5 minutes incubation.

CALCULATION :
With standard or calibrator.

$$\text{Conc. of unknown Sample} = \frac{\text{Concentration of Standard}}{\text{Abs. Standard - Abs. of Reagent Blank}} \times \text{Abs. of unknown Sample} - \text{Abs. of Reagent Blank}$$

CONVERSION FACTOR :
Mg/dl X 0.323 = mmol/l

CALIBRATION :
For the calibration of automated photometric systems the commercially available calibrator is recommended.

QUALITY CONTROL :
To ensure adequate quality, use of the commercially available control sera is recommended.

PERFORMANCE CHARACTERISTICS :
MEASURING RANGE :
The test has been developed to determine Phosphorus concentrations within a measuring range from 1 to 15 mg/dl (0.323 to 4.85 mmol/L). When values exceed higher limit of the range, such samples should be diluted 1 + 1 with NaCl solution (9 g/l) and the result multiplied by 2.

SPECIFICITY / INTERFERENCES :
No interference was observed by ascorbic acid up to 30 mg/dl (1703.4 µmol/L), bilirubin up to 20 mg/dl (342.0 µmol/L, hemoglobin up to 150 mg/dl (1.5 g/L) and Iron 1 mg/dl (0.18 mmol/L) triglycerides (1.71 mmol/L). A list of drugs and other interfering substances with Phosphorus determination has been reported by Young et al.

SENSITIVITY / LIMIT OF DETECTION :
The lower limit of detection is 1 mg/dl (0.323 mmol/L) .

PRECISION :

Intra-assay precision n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	6.83	0.02	0.29
Sample 2	6.46	0.06	0.93
Sample 3	5.70	0.05	0.88

Inter-assay precision n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	4.34	0.13	2.99
Sample 2	8.20	0.27	3.29
Sample 3	10.6	0.31	2.92

METHOD COMPARISON :
A comparison between Robonik Prietest Phosphorus (y) and a commercially available test (x) using 20 samples gave following results :

Linear Regression	:	y = 0.8347 x + 0.8282 mg/dl
Correlation Coefficient	:	r = 0.9291

REFERENCE RANGE :

Serum / Plasma	:	2.7 to 4.5 mg/dl	(0.87 to 1.45 mmol/L)
URINE	:	400 to 1300 mg/24h	(12.9 to 42 mmol/24h)

It is recommended that each laboratory should assign its own reference range.

LITERATURE :

1. Endres, D.B., Rude, R.K., *Mineral and bone metabolism*. Tietz Fundamentals of Clinical Chemistry, Burtis, C.A. and Ashwood, E.R. (W.B. Saunders eds. Philadelphia USA), (2001), 795.
2. Tietz, N.W. Clinical guide to laboratory tests, 3rd Ed, (W.B. Saunders eds. Philadelphia USA), (1995), 486.
3. Young, D. S., Effects of drugs on clinical laboratory tests, 4th Ed., AACC Press, (1995).

INSTRUMENT APPLICATION ***prietest TOUCH***
Name : PHOSP , Mod : END-P
Pri.: 340 , Sec.: 0
Temp: 37C , KF : 1.000
Vol : 500ul , Unit : mg/dl
Lag : 5 , Read : NA
Blk : Y, QC : Y, Norm : Y
Std : 1 , Concen :
Std.: 1 = 5.0
Normal HI = 4.5
Normal LO = 2.7
QCNH : *
QCNL : *
QCABH = *
QCABL = *
Rgnt. Linearity : 15
NOTE :
* Indicates user definable parameter.
NA Implies Not Applicable

PARAMETERS FOR INSTRUMENT SETTING	
TEST NAME	PHOSPHORUS
Reaction	End Point
Reaction Slope	Increasing
Wavelength 1	340 nm
Temperature	37°C
Zero Setting	Reagent Blank
Standard Conc.	5
Units	mg/dl
Sample Volume	10 µl
Reagent Volume	1000 µl
Incubation Time	5 minutes
Reference Range	2.7 to 4.5
Reagent Linearity	15

ROBONIK®
An ISO 9001 : 2008 Certified Company
An ISO 13485 : 2012 Certified Company

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