PHOSPHORUS

INORGANIC PHOSPHORUS

Intended use:

In vitro test for the quantitative determination of phosphorus in human serum, plasma and urine

Summary:

88% of the phosphorous contained in the body is localized in bone in the form of calcium phosphate as the apatite Ca2+[Ca3 (PO)]2-3. The remainder is involved in intermediary carbohydrate metabolism and in physiologically important substances such as phospholipids, nucleic acids and ATP Phosphorus occurs in blood in the form of inorganic phosphate and in organically bound phosphoric acid. The small amount of extracellular organic phosphorus is found almost exclusively in the form of phospholipids.

The ratio of phosphate to calcium in the blood is approximately 6:10. An increase in the level of phosphorus causes a decrease in the calcium level. The mechanism is influenced by interactions between parathormone and vitamin D. Hypoparathyroidism, vitamin D intoxication and renal failure with decreased glomerular phosphate filtration give rise to hyperphosphatemia. Hypophosphatemia occurs in rickets, hyperparathyroidism and Fanconi's syndrome. The preferred method for the determination of inorganic phosphorus is based on the formation of ammonium phosphomolybdate with subsequent reduction to molybdenum blue. Reagent stability problems often occur with this method. The method presented here is based on the reaction of phosphate with ammonium molybdate to form ammonium phosphomolybdate without reduction. The addition of an accelerator gives rise to a more rapid rate of reaction and the application of sample blanking yields more precise results.

Test principle:

Inorganic phosphate forms an ammonium phosphomolybdate complex having the formula$(NH_4)_3[PO_4(MoO_3)_{12}]$ with ammonium molybdate in the presence of sulfuric acid. The complex is determined photometrically in the ultraviolet region (340 nm).

Reagent Concentration:

R1:

H2SO4	280 mmol/l
NaCl	154 mmol/l
Detergent	2%

Preparation and stability:

R1: Ready for use.
Unopened Kits are stable up to the expiry date when stored at +2 to +8°C.
Onboard stability: R1: 30 days

Specimen:

Collect serum using standard sampling tubes
Heparinized or EDTA plasma

Stability:	1 day	at +20°C to +25°C
	4 days	at + 2°C to + 8°C

Urine: Stable for 8 hours at +15°C to +25°C

Limitations - interference:

Criterion: Recovery within ± 10% of initial value.
Icterus: No significant interference up to an index I 92 (approximate bilirubin concentration: 92 mg/dl).
Hemolysis: Significant positive interference at an index H 1100 (approximate hemoglobin concentration: 1100 mg/dl). Note: This interference results from inorganic phosphates produced by the action of phosphatases on organic phosphates, both of which are released from the red cells upon hemolysis.
Lipemia (Intralipid): No significant interference up to an index L of 825 (approximate triglycerides concentration: 1650 mg/dl). There is poor correlation between turbidity and triglycerides concentration.

Analytical sensitivity (lower detection limit)

1 mg/dl
The lower detection limit represents the lowest measurable phosphorus concentration that can be distinguished from zero.

Testing procedure:

Applications for automated systems are available on request.

Materials provided

- Working solutions as described above

Additional materials required

- Calibrators and controls as indicated below
- 0.9% NaCl

Manual Testing procedure		
Wavelength:	340 nm (334nm)	
Temperature:	+25°C/ +30°C/ +37°C	
Cuvette:	1 cm light path	
Zero adjustment:	One reagent blank for each series	
	Blank	Sample / Calibrator
R1	1000 µl	1000 µl
Sample / Calibrator	-	10 µl
Mix and incubate 5 minutes. Read the absorbance of specimen against reagent blank within 60min.		
Calculation:		
A sample / A Calibrator x Calibrator conc. = Phosphorus conc.		

Measuring/reportable range:

Serum 1 - 10 mg/dl
Determine samples containing higher phosphate concentrations via the rerun function. On instruments without rerun function, manually dilute samples with 0.9% NaCl or distilled or deionized water (e.g. 1:4). Multiply the result by the appropriate dilution factor (e.g. 4).

Expected values:

2.5-4.5 mg/dl (0.81-1.45 mmol/l)
Expected values for children are given in „Pediatric reference ranges“, 3rd edition, S.J. Soldin, C. Brugnara, I.M. Hicks, AACC Press.
Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference range. For diagnostic purposes, the phosphorus results should always be assessed in conjunction with the patient's medical history, clinical examinations and other findings.

Imprecision:

Reproducibility was determined using controls in an internal protocol. The following results were obtained:

Within run			
Sample	Mean (mmol/l)	SD (mmol/l)	CV %
Controlserum 1	1.25	0.016	1.36
Controlserum 2	1.57	0.012	0.76
Controlserum 3	2.11	0.014	0.66
Between Day			
Sample	Mean (mmol/l)	SD (mmol/l)	CV %
Controlserum 1	1.31	0.025	1.91
Controlserum 2	1.68	0.034	2.02
Controlserum 3	1.90	0.022	1.16

Method comparison:

A comparison of the BIOANALYTIC PHOS (y) with a commercial obtainable assay (x) gave the following result:
y = 1.030 x + 0.042; r = 0.991

Quality Control:

Control Serum:

BIOCON N	5 x 5 ml	#B10814
BIOCON P	5 x 5 ml	#B10817

The control intervals and limits must be adapted to the individual laboratory and country-specific requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

ISO 9001:2015
ISO 13485:2016

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Calibration:

S1: 0.9% NaCl

S2: BIOCAL H 5 x 3 ml #B11895

Calibration frequency:

A two-point-calibration is recommended in case of:

1-change of lot

2- quality control requirements

Literature:

1. Burtis C.A., Ashwood E.R.,(ed). Tietz Textbook of Clinical Chemistry, 2nd ed. Philadelphia, PA: WB Saunders, 1994:1909.
2. Fiske C.H., Subbarow Y. The colorimetric determination of phosphorus. J Biol Chem 1925;66:375-400.
3. Garb S. Clinical Guide to Undesirable Drug Interactions and Inter-ferences. New York, NY: Springer Publishing Co, 1971.
4. Glick M.R., Ryder K.W., Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation. Clin Chem 1 986;32:470-474.
5. Henry R. ed. Clinical Chemistry: Principles and Technics, 2nd ed. New York, NY: Harper & Row, 1974:723.
6. Külpmann W.R., Stummvoll H.K., Lehmann R. Elektrolyte, Klinik und Labor. Heidelberg: Verlag Klinisches Labor, 1993.
7. Taussky H.H., Schoor E.A. J Biol Chem 1953;202:675.
8. Tietz N.W., ed. Clinical Guide to Laboratory Tests, 3'° ed. Philadelphia, Pa: WB Saunders Company, 1995:486-487.
9. Tietz N.W., ed. Fundamentals of Clinical Chemistry. Philadelphia, Pa: WB Saunders Company; 1976:901.

Order information:

CC460	BPHO125	B24255	B28256	B33256	B80256
OL460	BPHO250	B25255	B30255	B34255	B80257
AB460	BPHO500	B25256	B30256	B35255	
KL460	B21255	B27255	B31255	B36255	
SH460	B21256	B27256	B32255	B37255	
CR460	B22255	B28255	B33255	B80255	

Manufacturer

Diaclinica Diagnostik Kimya.San.Tic.Ltd.Şti
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SYMBOLS

IVD	for in vitro diagnostic use only
LOT	lot of manufacturing
REF	code number
	storage at temperature interval
	expiration date (year/month)
	warning, read enclosed documents
	Read the directions

ISO 9001:2015
ISO 13485:2016