Ana-Chek® PHOSPHORUS

METHOD – UV-END POINT
PRODUCT CODE – LP01

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of Phosphorus in serum / plasma using UV-End Point method.

SUMMARY AND PRINCIPLE

The Inorganic phosphate is the fraction of clinical interest since its levels are closely tied to bone metabolism, renal function, vitamin D levels and parathyroid hormone status. Ana-Chek® Phosphorus is a single ready to use reagent kit for quantitative determination of phosphorus in human serum and plasma based on UV - end point method using ammonium molybdate.

Phosphorus + Ammonium Molybdate ⟶ Ammonium-phosphomolybdate complex

KIT COMPONENTS

Reagent 1 : Phosphorus Reagent
Reagent 2 : Phosphorus Standard (5 mg/dL)

REAGENT PREPARATION, STORAGE & STABILITY

Ana-Chek® Phosphorus is single ready to use reagent. The reagent kit should be stored at 2-8 ^{0}C and is stable till the expiry date indicated on the label.

PRECAUTIONS & HANDLING

The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent. Do not shake the reagent vigorously. Discard the reagent if the absorbance of the reagent exceeds 0.300 O.D. against D/W at 340 nm. Contamination of the reagent should be avoided.

TEST PARAMETERS

Name	Phosphorus
Reaction Type	End Point
Primary Wavelength	340 nm
Flow Cell Temp.	37 °C
Blank setting	Reagent
Blank abs. limit	< 0.300

Reagent Volume	1000 µl
Sample Volume	10 µl
Incubation Time	5 Min
Incubation Temperature	37 °C
Standard Conc.	5 mg/dL
Linearity	20 mg/dL

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls, Incubation chamber.

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Serum, heparinized or EDTA plasma can be used. Avoid haemolysed sample as haemolysis interferes with assay. Phosphorus in serum/ plasma is stable for 7 days at 2-8 ^{0}C and 3 weeks at -20 ^{0}C.

COMPONENTS OF REAGENT

Component	Concentration
Ammonium Molybdate	0.4 mmol/L
Sulphuric Acid	0.25 mmol/L
Stabilizers, inactive ingredients and surface-active agents.	-

ASSAY PROCEDURE

	Blank	Standard	Test
Reagent	1000 µl	1000 µl	1000 µl
Standard	NA	10 µl	NA
Sample	NA	NA	10 µl
Mix the reagent and sample/standard in the above-mentioned ratio.			
Incubate the assay mixture for 5 mins at 37^{0}C.			
Aspirate reaction mixture into flow cell and measure the absorbance.			

CALCULATION

$$\text{Phosphorus (mg/dL)} = \frac{\text{Abs. of sample} \times 5}{\text{Abs. of standard}}$$

REFERENCE VALUES FOR NORMAL PEOPLE

Adults : 3.0 – 5.0 mg/dL (0.87 – 1.45 mMol/L).
Children : 4.0 – 7.0 mg/dL (1.29 – 2.10 mMol/L).

PERFORMANCE CHARACTERISTICS

Measuring Range: The assay is linear between 0.2 - 20 mg/dL. If the Phosphorus value exceeds linearity limit (above 20 mg/dL), dilute the specimen suitably with normal saline and repeat the assay. In that case, assay value should be multiplied with the dilution factor to obtain correct Phosphorus value of the specimen.

Interference: There is no significant interference in samples containing bilirubin values upto 20 mg/dL. Haemolysis interferes as free and organic phosphates are released from RBC leading to false elevated results.

Precision: Precision studies has been carried out using quality control sera as shown below:

(n=10)	Within Run			Between Run		
Specimen Material	Mean (mg/dL)	SD (mg/dL)	CV %	Mean (mg/dL)	SD (mg/dL)	CV %
Low Value Serum	3.33	0.07	2.1	3.55	0.07	1.9
High Value Serum	7.46	0.04	0.5	7.51	0.06	0.7

Note: We recommend all the laboratories to establish its own accuracy and precision data.

QUALITY CONTROL

Inclusion of a normal value and abnormal value chemistry control serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides between run precision and accuracy data for Phosphorus. We recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

PRECAUTIONS

1. Contaminated glassware is the greatest source of error. Disposable plastic wares are recommended for the test.
2. Discard the working reagent if its absorbance is >0.300 against distilled water at 340 nm.
3. If the phosphorus value exceeds 20 mg/dL then dilute the specimen suitably with normal saline and repeat the assay. In such case the assay value should be multiplied by the dilution factor to obtain correct phosphorus value.
4. Strong lipaemic and haemolysed sera should not be used.

BIBLIOGRAPHY

1. Tietz NW, ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia, Pa : W.B. Saunders, 1995 : 486 - 487.
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3. Gamst, O. and Try, K., Scand. J. Clin Lab. Invest. 40, 1980.
4. Amador, E and Urban, J., Clin. Chem. 18, 60 (1977).

Symbol	Explanation	Symbol	Explanation
	Manufactured By	IVD	In Vitro Diagnostic Use
LOT	Lot Number		Read Instructions Before Use
REF	Catalogue Number		Storage Temperature
	Manufacturing Date	Σ	Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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ISO 9001: 2015
ISO 13485: 2016
GMP
CE