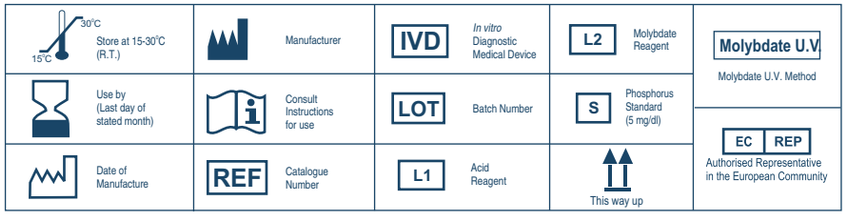
SBio PHOSPHORUS KIT

(Molybdate U.V. Method)

(For invitro diagnostic use only)

REF	90650075	90662150
Pack Size	75 ml	2 x 150 ml

CE



INTENDED USE

Phosphorus Kit is used for the determination of Inorganic Phosphorus in serum, plasma and urine.

PRINCIPLE OF THE TEST

Phosphate ions in an acidic medium react with ammonium molybdate to form a phosphomolybdate complex. This complex has an absorbance in the ultraviolet range and is measured at 340 nm. Intensity of the complex formed is directly proportional to the amount of inorganic phosphorus present in the sample.

Phosphorus + Ammonium Molybdate ⟶ Phosphomolybdate Complex

CLINICAL SIGNIFICANCE

Phosphorus is a nonmetallic chemical element essential to metabolize protein, calcium, and glucose (sugar). It is needed for bone and tooth formation (85% of phosphorus is found in the skeletal system), cell growth (and production of DNA/RNA), heart muscle contraction, and kidney function (waste filtration). Phosphorus helps the body to utilize vitamins, assists other body functions to convert food into energy, and maintains the blood's pH (acidity). Increased level of phosphorus is found in hypoparathyroidism, renal failure, bone metastasis and liver diseases. Decreased levels are found in hyperparathyroidism, rickets and Vitamin D deficiency.

PRESENTATION	75 ml	2 x 150 ml
L1 : Acid Reagent	60 ml	2 x 120 ml
L2 : Molybdate Reagent	15 ml	2 x 30 ml
S : Phosphorus Standard (5 mg/dl)	5 ml	5 ml

COMPOSITION

Sulphuric Acid 700 mM; Ammonium Molybdate 0.4 mM; Detergent.

STORAGE / STABILITY

Contents are stable at R.T. (15 - 30°C) till the expiry mentioned on the labels.

REAGENT PREPARATION

Reagents are ready to use.

Working reagent: Pour the contents of 1 bottle of L2 (Molybdate Reagent) into 1 bottle of L1 (Acid Reagent). This working reagent is stable for at least 6 months when stored at 2-8°C. Upon storage the working reagent may develop a slight blue colour however this does not affect the performance of the reagent.

Alternatively for flexibility as much of working reagent may be made as and when desired by mixing together 4 parts of L1 (Acid Reagent) and 1 part of L2 (Molybdate Reagent). Alternatively 0.8 ml of L1 and 0.2 ml of L2 may also be used instead of 1 ml of the working reagent directly during the assay.

SAMPLE MATERIAL

Serum, Heparinized / EDTA Plasma or urine is required. Acidify the urine with a few drops of conc. Hydrochloric acid and dilute 1+19 before the assay, (results x 20).

SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.

This product requires the handling of human specimen. It is recommended that all human sourced material are considered potentially hazardous and are handled in accordance with the OSHA standard on blood borne pathogens.

Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

Handle specimen, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

PROCEDURE

Wavelength/filter	:	340 nm (Hg 365 nm)
Temperature	:	R.T.
Light path	:	1 cm

MATERIAL REQUIRED BUT NOT PROVIDED

General laboratory instrumentation like Spectrophotometer/Analyzer, Thermostatic Cuvette holder, Cuvettes, Micropipettes, Test tubes, Waterbath, Stopwatch/Timer.

Pipette into clean dry test tubes labeled as Blank (B), Standard (S) and Test (T):

Addition Sequence	B (ml)	S (ml)	T (ml)
Working Reagent	1.0	1.0	1.0
Distilled Water	0.01	--	--
Phosphorus Standard (S)	--	0.01	--
Sample	--	--	0.01

Mix well and incubate at R.T for 5 minutes. Measure the absorbance of the Standard (Abs. S), and Test Sample (Abs. T) against the Blank, within 60 minutes.

CALCULATIONS

$$\text{Phosphorus in mg/dl} = \frac{\text{Abs.T}}{\text{Abs.S}} \times 5$$

QUALITY CONTROL

The following process is recommended for QC during the assay of Phosphorus. *Define and establish acceptable range for your laboratory.

1. Two levels of control (Normal and Abnormal) are to be run on a daily basis.
2. If QC results fall outside acceptance criteria, recalibration may be necessary.
3. Review QC results and run acceptance criteria following a change of reagent lot.

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity:

This procedure is linear upto 20 mg/dl. If values exceed this limit, dilute the sample with distilled water and repeat the assay. Calculate the value using the proper dilution factor.

Limit of detection:

The limit of detection for Phosphorus is 0.1 mg/dl.

Interferences:

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Precision:

Precision studies were performed with two controls using NCCLS protocol EP5-A. The results of the precision studies are shown below:

Sample	Within-run		Between-run		Total	
	Mean	CV%	Mean	CV%	Mean	CV%
Control 1	3.66	3.23	1.15	5.86	4.81	9.09
Control 2	6.25	2.86	1.95	4.73	8.2	7.59

Method comparison:

Comparative studies were done to compare our reagent with another commercial Phosphorus Assay. No significant differences were observed. Details of the comparative studies are available on request.

REFERENCE RANGE

Serum (Adults)	:	2.5 - 5.0 mg/dl
(Children)	:	4.0 - 6.5 mg/dl
Urine	:	0.3 - 1.0 g/24 hours

It is recommended that each laboratory establish its own normal range representing its patient population*.

NOTE

Inorganic Phosphorus is reported to be stable in serum for 7 days at 2-8°C.

Hemolysis interferes with the test.

Use clean glassware washed with N/10 HCl as detergents may contain phosphate ions. The reagent may be used in several automated analyzers. Instructions are available on request. Do not use turbid, deteriorated or leaking reagents.

REFERENCES

1. Fiske, C.H., Subbarow, Y, (1925) J. Biol. Chem. 66 : 375.
2. Goodwin, J.F., (1970) Clin. Chem. 16(19) : 776.

Mfd. for:

Singapore SB Biosciences PTE Ltd.

11 Yishun Street 51, # 04-23, The Criterion, Singapore 767971.

EC REP

CMC Medical Devices & Drugs S.L.,
C/ Horacio Lengo No. 18, CP 29006, Malaga, Spain.

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