PHOSPHORUS liquid

UV Colorimetric Method

2 x 100 ml CL33-200S

INTENDED USE

Kit for quantitative determination of Phosphorous in serum and urine.

CLINICAL MEANING

Phosphorus can be found in high concentrations in the organism (650g) in many different chemical forms. Its importance is related to different metabolisms: bones, lipids, glycols. Around 80% of phosphorus can be found in skeletal tissue and the rest is in the muscular tissue and organic liquids. Phosphorus is absorbed with foods and the majority is eliminated through urine. Its metabolism is strictly linked with the metabolism of calcium and it is regulated by the PHT (para thyroid hormone), by vitamin D and by calcitonin. An increase in phosphorus leads to a decrease of calcium levels. The fraction that is typically determined in a clinical laboratory is the inorganic part, found in serum. Low phosphorus levels can indicate rickets, Fanconi syndrome and hyperparathyroidism. An increase in phosphorus levels can lead back to vitamin D intoxication, hypoparathyroidism and renal failure with reduced glomerular filtration.

PRINCIPLE

In an acid medium, inorganic phosphorus reacts with molybdate ammonium to form phosphomolybdic ammonium, whose absorbance is directly proportional to the concentration on phosphorus in the sample.

SAMPLE

Fresh, non hemolysed serum. Hemolysed or jaundiced samples cannot be utilised. The only anticoagulant that can be used is heparin: the other ones may diminish the value of inorganic phosphorus. Separate serum from blood clot as soon as possible.

STABILITY: up to 7 days at 2-8°C, three weeks at -20°C. Urine: 24/h.

Diluted urine 1:10 with distilled and acidified water (2-3 drops of HCI 23%).

REAGENTS

Only for in Vitro diagnostics. Liquid mono-reagent ready to use.

Package contents	**CL33-200S**
REAGENT 1 Molybdate ammonium < 1 %, nitric acid 66% < 3 %	2 x 100 ml
STANDARD (Std) Phosphorous 5 mg/dl (1,615 mmol/L)	1 x 4 ml

STABILITY: store at 2-8°C and protect from light to keep the reagents stable up to the expiration date on the label.

NECESSARY ITEMS – NOT PROVIDED

Usual laboratory equipment: UV/VIS Spectrophotometer with temperature control; automatic micropipettes; Optical glass cuvettes or, alternatively, disposable ones in optical polystyrene; Saline solution.

MANUAL ASSAY PROCEDURE

Wavelength:	340 nm
Optical Path:	1 cm
Reading:	Against blank reagent
Temperature:	25/30/37°C
Reaction:	end point
Sample/Reagent Ratio:	1/100

Bring the reagent to the chosen temperature for the analysis.
Pipette in cuvette:

	Blank	Sample	Standard
Reagent 1	1000 µL	1000 µL	1000 µL
Distilled water	10 µL		
Sample		10 µL	
Standard			10 µL

Shake and incubate for 3 minutes at 37°C or 5 minutes at room temperature. Then read the extinction of the standard (AbsStd) and of the sample (AbsS) against the blank reagent. The coloration is stable for a least 15 minutes at room temperature.

Reaction volumes can be proportionally varied without any change in calculation. This leaflet describes the usage of the kit in manual. In case of usage with analysers, please request the specific applications. Calibration with aqueous standards may cause a systematic usage error with certain automatic instruments. A proteic human calibrator is recommended.

CALCULATION

Serum:

[mg/dl] Phosphorus = AbsC / AbsStd x 5

Urine:

Phosphorus mg/24h = AbsC / AbsStd x 5 x 10 (dil. factor\) x Vol Urine 24/h (dl) =

Conversion factor mg/dl x 0.323 = mmol/L

REFERENCE VALUES

Serum:
Children up to 12 years old: 4.0-7.0 mg/dL
Adults: 2.7-4.5 mg/dL 0.87-1.45 mmol/L
Urine:
Adults: 400-1300 mg/dl 12.9-42.0 mmol/24h

These values are only for reference. Each laboratory should define their own reference values.

QUALITY CONTROL – CALIBRATION

All Clinical Chemistry laboratories should implement a quality control program. Control serums of human origin are available for this purpose on request:
PRE-NORM serums with normal values
PRE-PATH serums with pathological values
If the method requires it, a multiparameter calibrator of human origin is available.

PERFORMANCE CHARACTERISTICS

Linearity: 20 mg/dl. For higher concentrations, repeat the analysis on a diluted sample (1:2 with saline solution) and multiply the result by 2.
Measurable limit: 0,25 mg/dL
Sensitivity: 0,1 mg/dL = 0,0052 at 340 nm
Precision:

Within run (n=10)	Average [mg/dL]	CV %
Average level	3,5	1,4
High level	7,8	0,9

Between run (n=20)	Average [mg/dL]	CV %
Average level	3,5	2,3
High level	7,7	2,7

Interferences: Triglycerides (500 mg/dl) do not interfere.
Glucose (600 mg/dl) does not interfere.
Albumin (20 g/dl) does not interfere.
Significant interference with Bilirubin from 12 mg/dl.
Significant interference with Haemoglobin from 0.15 g/dl.
The presence of Hb and bilirubin in said concentrations, causes a 10% increase of inorganic phosphorus.

Correlation coefficient: (r): 0.999 (n=60)
Linear regression:y = 1.02x - 0.06 (n=60)

DISPOSAL

The product must be used for professional analysis only. The product must be disposed of according to national/international laws.

WARNINGS AND PRECAUTIONS

The product, according to current legislation, is not classified as dangerous. The total concentration of non-active components (preservatives, detergents, stabilisers) is lower than the required limits. Nonetheless, please handle the product with care, according to the usual laboratory rules. Avoid ingestion and contact with skin.

REFERENCES

1. Erthinghsausen G., Clin. Chem., 18, 263 (1972).
2. Vassault, A. et al. Ann. Biol. Clin., 44, 686 (1986).
3. Young, D.S., et al. Clin. Chem. 21:1D (1975).

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KEY SYMBOLS

IVD	In Vitro diagnostic medical device
LOT	batch number
REF	catalog number
	temperature limits
	use by
	caution
	consult accompanying documents

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