

Phosphorus

Phosphomolybdate. UV. Liquid

Store at 2-8 °C

Configuration

REF	HB014
VOL	2 x 125 mL
Reagent 1	2 x 125 mL
Standard	1 x 5 mL

Intended use

The Cypress Diagnostics kit Phosphorus is an in vitro diagnostic medical device intended to be used for the quantitative measurement of phosphorus in human serum, plasma or urine. The device is not automated. The measurement of phosphorus is intended to be used to aid in the diagnosis and monitoring of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance, in patient risk population. This kit is intended to be used by healthcare professionals in a laboratory-based testing environment. For *in vitro* diagnostic use only. For professional use only.

Clinical significance

The majority of the body phosphorus is found in the bone as hydroxyapatite. The remainder of the phosphate is present as organic phosphate and phosphate esters. Phosphorus is involved in the intermediary metabolism of carbohydrates and is a component of other physiologically important substance. Thus, increased serum phosphorus may occur in hypervitaminosis, hypoparathyroidism, and renal failure. Reduced serum phosphorus levels are seen in rickets (vitamin D deficiency), hyperparathyroidism, and Fanconi's syndrome.

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Principle

Inorganic phosphate reacts in acid medium with ammonium molybdate to form a phosphomolybdate complex with yellow color. The intensity of the color formed is proportional to the inorganic phosphorus concentration in the sample.

Reagent composition

Reagent 1	Sulfuric acid (210 mM) Ammonium molybdate (0,40 mM) Detergent
Standard	Phosphorus aqueous (see value on label)

Precautions

- Reagent 1: Danger. H314: Causes severe skin burns and eye damage. P280: Wear protective gloves/protective clothing/eye protection/face protection. P501: Dispose of contents/container in an appropriate container observing applicable local regulations.
- All body fluid samples should be considered potentially infectious materials and the appropriate precautions should be taken. Wear personal protective equipment such as gloves, safety glasses, lab coats or aprons when working with possible biohazard contaminants.
- Use Good Laboratory Practices (GLP) when handling this product.
- Please refer to the MSDS, available on our website, for further information.

Preparation

Reagent and standard are ready to use.

Storage, stability and disposal

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2-8 °C.

Handle standard very carefully to prevent contamination. The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 340 nm $\geq 0,54$, the reagent should be discarded.

Do not use the product if deterioration or contamination is suspected or beyond the expiration date or open container stability period. Dispose unused or deteriorated product and waste in compliance with local regulations.

Additional material required but not provided

- Spectrophotometer or colorimeter. Minimum analyzer specifications:
Measuring at 340 nm
Linear measuring range: 0 - 2 AU
- Cuvettes, matching the analyzer used (1,0 cm light path)
- General laboratory equipment^{Note 4}

Samples

Sample type: human serum, plasma or urine.

- Serum or plasma, free of hemolysis and separated from cells as rapidly as possible. Stability: 7 days at 2 - 8 °C.

- Urine: collect the specimen into a bottle containing 10 mL of 10% v/v hydrochloric acid (HCl) to avoid phosphate precipitations. Adjust to pH 2. Dilute the sample 1:10 with distilled water. Mix. Multiply the result by 10 (dilution factor). Stability: 10 days at 2 - 8 °C.

Procedure

Make sure the reagents and samples are at room temperature.

1. Wavelength 340 nm; Temperature 25, 30, 37 °C; Cuvette (1 cm light path).
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

For Blank	1 mL Reagent
For Standard ^{Note 3,5}	10 μ L Standard + 1 mL Reagent
For Sample	10 μ L Sample + 1 mL Reagent

Mix and incubate 5 min. at 25, 30 or 37 °C. Measure the absorbance (A) of the samples and the standard against blank.

Calculation

Serum and plasma:

$$\text{Phosphorus (mg/dL)} = \frac{A_{\text{Sample}} - A_{\text{Blank}}}{A_{\text{Standard}} - A_{\text{Blank}}} \times \text{stand.conc.} \left(\frac{\text{mg}}{\text{dL}} \right)$$

Urine (24h):

Phosphorus (g/24h)

$$= \frac{A_{\text{Sample}} - A_{\text{Blank}}}{A_{\text{Standard}} - A_{\text{Blank}}} \times \text{stand. conc.} \left(\frac{\text{mg}}{\text{dL}} \right) \times \text{vol (dL) urine 24h} \times 0,001 \times f^*$$

*f = dilution factor

Conversion Factor:

mmol/L = 0,323 x mg/dL

mmol/24h = 32,3 x g/24h

Quality control

Control sera are recommended for the qualification of the reagents and to monitor the performance of assay procedures. Next to legal requirements, we recommend to perform Quality Control on a daily basis and after each calibration.

Use Biochemistry Normal and Pathological Controls Specific (HBC01-S, HBC02-S). If other controls (not manufactured by Cypress) are used, they have to be validated by the user as they can vary. Prepare and measure these controls the same as samples. Measure at least one replicate per control.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Do not continue testing as the results will be invalid. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

Reference values

Serum - Children	4,0 - 7,0 mg/dL (1,29 - 2,26 mmol/L)
Serum - Adults	2,5 - 5,0 mg/dL (0,81 - 1,62 mmol/L)
Urine - Adults	0,4 - 1,3 g/24h

These values are for orientation purpose. Each laboratory should establish its own reference range.

Performance characteristics

Measuring range: from 0 mg/dL (detection limit) to 35 mg/dL (linearity limit). If the obtained results are greater than 35 mg/dL, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

Precision:

	intra-assay (n=20)		inter-assay (n=20)	
	Mean (mg/dL)	SD	Mean (mg/dL)	SD
Mean (mg/dL)	4,09	7,12	4,11	7,09
SD	0,03	0,046	0,09	0,06
CV (%)	0,62	0,80	2,15	0,80

Sensitivity: 1 mg/dL = 0,0798 AU

Accuracy: Results obtained using CYPRESS DIAGNOSTICS reagents did not show systematic differences when compared with other commercial reagents. The results of the performance characteristics depend on the analyzer used.

Interferences

Hemolyzed specimens are unacceptable. A list of drugs and other interfering substances with phosphorus determination has been reported by Young et al.

Notes

1. For best use of this kit on a Cypress Diagnostics analyzer, we kindly advise to follow the application sheets of the respective analyzer. Please log in to our website (www.diagnostics.be) as a registered user to download the latest application sheets, which are located under the section of the corresponding analyzer. Compatible Cypress analyzers: CYANsmart, CYANstart, CYANexpert 130, CYANvision.



2. In case other instruments (not manufactured by Cypress Diagnostics) are used, the laboratory is responsible to validate the reagents in this kit on those analyzers before testing patient samples.
3. Calibration with the aqueous standard may cause a systematic error in automatic procedures. In this case, it is recommended to use a serum based Biochemistry Calibrator Specific (HBC03-S).
4. Most of the detergents and water softening products used in the laboratories contain chelating agents and phosphates. It is recommended to rinse glassware in diluted nitric acid and water before using.
5. Use clean disposable pipette tips for its dispensation.

Bibliography

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3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press 1995
4. Young DS. Effects of diseases on Clinical Lab. Tests, 4th ed AACC 2001
5. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999
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Notice: Any serious incident that has occurred in relation to the device shall be reported to Cypress Diagnostics and the competent authority of the Member State in which the user and/or patient is established.

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