Phosphorus – Instructions for use

Distributed by: ISE S.r.l. CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

IVD CE

6 x 50 mL • REF A-R0200000701
3 x 18,5 mL • REF R3330000023

INTENDED USE
Product for use in the quantitative determination in vitro of the concentration of Inorganic phosphorus in human serum or urine. The results of the test must always be interpreted in conjunction with the clinical picture. For professional use only.

CLINICAL SIGNIFICANCE
Phosphorus is an important element present in the human body in the form of inorganic or organic phosphate. In serum exists in the form of both monovalent and divalent phosphate anions. About 10 % of the phosphate present in serum is bound to proteins, 35 % is found in combination with sodium, calcium and magnesium and the remaining percentage is free. Phosphate is one of the main components of hydroxyapatite present in bones, plays an important role as a high-energy phosphate bond and is a vital component for the activity of numerous enzyme systems. Hypophosphatemia is a relatively common condition in the nosocomial population, detectable in several causes such as: stimulation of insulin secretion that promotes the transport of phosphates into cells and respiratory alkalosis. A loss of phosphates by the kidney can be the cause of a low level of phosphates in serum. Hyperphosphatemia is usually related to renal failure. A decrease in glomerular filtration limits renal phosphate excretion resulting in the development of hyperphosphatemia.

PRINCIPLE
The method measures the absorbance at 340 nm of unreduced phosphomolybdate and allows the determination of inorganic phosphates in serum. Inorganic phosphorus reacts, in the presence of sulfuric acid, with molybdate ammonium to give an unreduced complex that can be read at 340 nm.
Inorganic phosphorus + H_2SO_4 + ammonium molybdate $\rightarrow$ Phosphomolybdate

REAGENTS
A-R0200000701- 6 x 50 mL
Reagent: n° 6 vials x 50,0 mL ready for use
R3330000023 - 3 x 18,5 mL
Reagent: n° 3 vials x 14,0 mL ready for use

Concentrations

Reagent:			
	Conc.	**U.M.**	
Sulphuric Acid	0,50	N	
Ammonium molybdate	0,61	mM	**GHS05***

* _ ***Warning***: DANGER - *Contains Sulphuric Acid (CAS 7664-93-9)*
H314 - Causes severe skin burns and eye damage.
P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 - Immediately call a POISON CENTER / doctor.
P321 - Specific treatment (see on this label).
P501 - Dispose of contents/container in accordance with local/ Regional /national / international regulations.

Precautions
Kit for professional laboratory use, used only by qualified and properly trained technical personnel, under the supervision of a doctor in charge of the laboratory. In addition to risk indications related to the active components, reagents may contain inactive components such as preservatives and detergents. The total concentration of these components is lower than the limits reported in the EC 1272/2008 Regulation and subsequent amendments and additions. However, it is recommended to handle reagents according to the standards of good laboratory practice

Reports of serious incidents
In the event of a serious incident in relation to the use of the device, please inform the manufacturer (via your distributor) and the competent authority of the European Union member state where the incident occurred. For other jurisdictions, reporting must be made in accordance with regulatory requirements. Reporting serious incidents helps provide more information about the safety of the diagnostic medical device.

Storage and stability
Store at 2 - 8°C and protect from direct light. When correctly stored, the reagents are stable up the expiry date reported on the label. A slight variation in the composition of the reagent may occur between batches, but this has no effect on the test results.
After opening, the vial are stable 30 days if recapped immediately and protected from contamination, evaporation, direct light and stored at correct temperature.

SAMPLE COLLECTION
Type of sample and storage
Use samples of fresh, hemolysis-free serum. Inorganic phosphorus is stable in serum for 5 days at 2 - 8°C and for 3 weeks at - 20°C. The freshly collected urine should be diluted with distilled water in the proportion of 1:20 (1 part urine with 19 parts water) then immediately analyzed.

Precaution
All human samples must be handled and disposed of as potentially infectious materials.

PROCEDURE
Quality control
Control sera of known Magnesium are commercially available for quality control, including certificates of analysis showing values and confidence limits. Normal and pathological control sera "Normal control serum" cod. R0400000006 and "Pathological control serum" code R0400000106. The values obtained must be contained within the acceptability range. In case of incorrect results check the following points:
- Cleanliness of glassware.
- Wavelength setting.
- Expiration date of reagents.

Automation
Although this device has been developed and manufactured to be used by manual method and instrumental systems, it can also be used in combination with other instrumental devices that are able to meet the requirements indicated in the paragraph "Reaction conditions / Technique".
All applications that are not explicitly approved cannot be guaranteed in terms of performance and will therefore have to be evaluated by the user

Calibration
For calibration use the "Multicalibrator code R0300000006. For the use on I.S:E: srl instruments, the calibration is recommended to be done every 10 days.

Traceability:
The Phosphorus traceability is reported in the package insert supplied with the ""Multicalibrator".

Reaction conditions
Wavelength (primary): 340 nm
Temperature: 37°C

Technique – Procedure with Serum as starter
Bring the reagents to the reaction temperature.

	U.M.	**Calib.Serum**	**Sample**	**Blank**
Reagent	µL	1000	1000	1000
Calib.Serum	µL	10	-	-
Sample	µL	-	10	-
Blank	µL	-	-	10

Mix then wait 3 minutes before reading.
If the blank reagent exceeds 0,800 D.O. at 520 nm, discard the reagent.
Read the absorbances of the sample (sample D.O.) and of the Calibration Serum (D.O. calibration serum) subtracting the absorbance of the reagent white. The final color is stable 30 minutes away from direct light.
The reaction volumes can be varied proportionately, the calculation remaining unchanged.

Results
The concentration of Magnesium is obtained through the following formula:

$$\frac{\text{D. O. Sample}}{\text{D.O. Calibration serum}} \times \text{Calibrator conc.} = \text{Phosphorus mg/dL}$$

NORMAL VALUES
Serum
- Adults 2.3 – 4.0 mg/dL (0.74 – 1.2 mmol/L)
- Children: 4.0 – 5.4 mg/dL (1.29 – 1.74 mmol/L)

Urine
- Adults: 0.4 – 1.3 g/24 h (12.9 – 4.02 mmol/24 h)

Sclavo Diagnostics International
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Reagents included in the kit
The reagent is described above.

Materials required but not supplied in the kit
Calibrators and controls.

ANALYTICAL CHARACTERISTICS / PERFORMANCE

Linearity
The reaction is linear up to 30 mg/dL. If the value in the sample exceeds the linearity limit of the method, dilute the sample with saline and multiply the result by the dilution factor

Accuracy-Recovery
Accuracy studies were performed on normal samples to which known amounts of inorganic phosphorus were added. The results indicate an average recovery of 100,2 %.

Interference
The high dilution of the sample with the reagent minimizes interference due to lipids. Bilirubin below 20 mg/dL does not interfere with the reaction, hemoglobin affects the reaction at a concentration higher than 50 g/L. For other interfering substances, refer to the Bibliography.

Precision

Within-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mg/dL	1,51	0,042	2,76%	30
High	mg/dL	5,53	0,105	1,90%	30
Between-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mg/dL	1,51	0,063	4,14%	20
High	mg/dL	5,53	0,269	4,87%	20

Sensitivity
At a λ 340 nm corresponds a concentration of 0.043 mg/dL of phosphorus.

Comparative method
The phosphorus reagent was compared with the method of Daly J.A. and Ertingshausenm (1) modified by Amador and Urban (4) with the following results: Regression line: y = 0.844x – 0.35; Correlation coefficient r = 0.968; Tested samples n° = 71.

Disposal of reagent
Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

Manufacturer:
Sclavo Diagnostics International
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Symbols used in IFU and Packaging	
IVD In vitro diagnostic medical device vitro	Manufacturer
REF Catalogue Number	Instruction for use
LOT Lot Number	Temperature limitation
Expiration date	

References

1. Daly JA, Ertingshausen G. Clin Chem 1972; 18: 263-265.
2. Van der Stock J. Poster at European Congress of Clinical Chemistry, Budapest 1983.
3. Pasquinelli F. Diagnostica e Tecniche di Laboratorio, Rosini Editrice, Firenze 1969; 1070-1076.
4. Amador E, Urban J. Clin Chem 1972; 18: 601-604.

REVISION	DATE	CHANGE
Rev.A	12/2022	New Issue for IVDR Regulation (UE) 2017/746 compliance