

**DIAGNOSTIC KIT
FOR DETERMINATION OF
INORGANIC PHOSPHORUS
CONCENTRATION**



OS – PHOSPHORUS

INTRODUCTION

Phosphorus is present in all body cells as a component of nucleic acids, phospholipids and phosphoproteins. Phosphorus is essential for intracellular storage and conversion of energy (ATP, creatine phosphate) and participates in carbohydrates metabolism. In the blood phosphorus is present as a mixture of inorganic phosphates HPO_4^{2-} and $H_2PO_4^-$. Besides phosphorus and calcium constitute mineral portion of bone. Continuous flux of phosphorus in organism is controlled by parathyroid hormone (PTH), vitamin D and calcitonin. Phosphorus serum level abnormalities are caused usually by disorders of vitamin D metabolism or parathyroid and kidney diseases.

METHOD PRINCIPLE

Direct phosphomolybdate reaction without deproteinization. Phosphate ions form with molybdate ions in acid solution proportional amounts of unreduced phosphomolybdate complex. The concentration of the complex formed is determined by measuring its absorbance.

REAGENTS

Package
1-Reagent 3 x 53 ml

The reagent is stable up to the kit expiry date printed on the package when stored at 2-8°C. The reagent is stable for 12 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

Concentrations in the test

ammonium molybdate 0.4 mmol/l
sulphuric acid 150 mmol/l
hydrochloric acid 100 mmol/l
detergents

Warnings and notes

- Product for in vitro diagnostic use only.
- Contaminated glassware is the greatest source of error. Disposable plastic ware is recommended for the test.
- 1-Reagent meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008.

Ingredients:

1-Reagent contains sulfuric acid (VI) and hydrochloric acid.

Danger



H314 Causes severe skin burns and eye damage.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing.

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 or doctor.

SPECIMEN

Serum, heparinized plasma (recommended: heparine lithium, sodium or ammonium salt) free from hemolysis, 24-hours urine.

Serum is the preferred specimen. Level of inorganic phosphate in heparinized plasma is about 0.2 to 0.3 mg/dl (0.06 – 0.10 mmol/l) lower than in serum.

Serum should be separated from red blood cells as soon as possible after blood collection, because erythrocytes contain several times higher phosphate concentration than normal serum.

Urine preparation: To prevent phosphate precipitation in urine, specimens should be collected in HCl, 20-30 ml of 6 mol/L for 24-h specimen. Then dilute 1 part of acidified urine with 10 parts of distilled water. Multiply the result by the dilution factor.

Serum and plasma can be stored up to 7 days at 2-8°C. For longer storage samples should be frozen at -20°C.

24-hours urine samples can be stored up to 7 days at 2-8°C. Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

This reagent may be used in automatic analysers Olympus AU400/AU640.

1-Reagent is ready to use.

For reagent blank deionized water is recommended.

APPLICATION

Reagent ID: 022

Specific Test Parameters											
General		LIH	ISE	Range							
Test name:		PHOS				Type:		Serum		Operation: Yes	
Sample: Volume	3	μL	Dilution	10	μL	Pre-Dilution Rate:	1				
Reagents: R1 Volume	300	μL	Dilution	0	μL	Min OD			Max OD		
R2 Volume	0	μL	Dilution	0	μL	L	-2.0000	H	2.5000		
						Reagent OD Limit:					
Wavelength: Pri.	340		Sec.	700		First L	-2.0000	First H	2.5000		
Method:	END						Last L	-2.0000	Last H	2.5000	
Reaction Slope:	+						Dynamic Range:				
Measuring Point 1: First	0		Last	27		L	0.23	H	20		
Measuring Point 2: First							Correlation Factor:				
Linearity:							A	1.000	B	0.000	
No-Lag-Time:							On-board Stability Period:		84		

Specific Test Parameters											
General		LIH	ISE	Range							
Test name:		PHOS				Type:		Serum			
Value/Flag:		#		Level L:		#		Level H:		#	
Normal Ranges:											
	Sex	Age L Year	Month	Age H Year	Month	L			H		
1.	#	#	#	#	#	#			#		
2.	#	#	#	#	#	#			#		
3.	#	#	#	#	#	#			#		
4.	#	#	#	#	#	#			#		
5.	#	#	#	#	#	#			#		
6.	#	#	#	#	#	#			#		
7. None Selected						#			#		
8. Out of Range						#			#		
						L			H		
Panic Value:		#		#		Unit:		mg/dl		Decimal Places: 1	

Calibration Specific					
General ISE					
Test name:		PHOS		Type: Serum	
Calibration Type:		3AB		Formula: Polygonal	
Counts:		3		Process: CONC	
Point 1:	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
Point 2:	#		**	-2.0000	2.5000
Point 3:	#		*	-2.0000	2.5000
Point 4:			*	-2.0000	2.5000
Point 5:					
Point 6:					
Point 7:					
1-Point Cal.Point:				Slope Check: None	
Advanced Calibration:		#			
MB Type Factor:				Calibration Stability Period: 84	

User defined
* Calibrator value
** Deionized water should be used as calibrator 1

REFERENCE VALUES ⁷

serum / plasma	mg/dl	mmol/l
age: 0 – 10 d	4.5 – 9.0	1.45 – 2.91
10 d – 24 mo	4.5 – 6.7	1.45 – 2.16
24 mo – 12 y	4.5 – 5.5	1.45 – 1.78
12 – 60 y	2.7 – 4.5	0.87 – 1.45
> 60 y males	2.3 – 3.7	0.74 – 1.20
> 60 y females	2.8 – 4.1	0.90 – 1.32
24-hours urine	g/24h	mmol/24h
	0.4 – 1.3	12.9 – 42.0

It is recommended for each laboratory to establish its own reference ranges for local population.

Phosphorus concentration in 24-hours urine – calculation

phosphorus concentration in 24-hours urine [g/24h]	=	phosphorus concentration in sample of 24-hours urine [mg/dl]	x	urine volume of 24-hours urine [dl/24h]	÷	1000
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QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) for determination in serum or CORMAY URINE CONTROL LEVEL 1 (Cat. No 5-161) and LEVEL 2 (Cat. No 5-162) for determination in urine with each batch of samples.

For the calibration of automatic analysers systems the CORMAY MULTICALBRATOR LEVEL 1 (Cat. No 5-174; 5-176) and LEVEL 2 (Cat. No 5-175; 5-177) is recommended.

The calibration curve should be prepared every 12 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analyser Olympus AU400. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 0.23 mg/dl (0.074 mmol/l).
- **Linearity:** up to 20 mg/dl (6.46 mmol/l).
For higher concentration dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.
- **Specificity / Interferences**
Haemoglobin up to 0.16 g/dl, ascorbate up to 62 mg/l, bilirubin up to 15 mg/dl and triglycerides up to 1000 mg/dl do not interfere with the test.

Precision

Repeatability (run to run) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	4.39	0.04	0.86
level 2	7.42	0.07	0.99

Reproducibility (day to day) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	4.38	0.05	1.07
level 2	7.15	0.07	1.04

Method comparison

A comparison between phosphorus values for samples obtained on Olympus AU400 (y) and obtained on Advia 1650 (x) using 24 samples gave following results:

$$y = 0.9316x + 0.3171 \text{ mg/dl};$$

$$R = 0.997 \quad (R - \text{correlation coefficient})$$

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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