Phosphate FS*

Diagnostic reagent for quantitative in vitro determination of phosphorus in serum, plasma or urine on BioMajesty JCA-BM6010/C

Order Information

Cat. No. 1 5211 99 10 962
R1: 6 x 315 tests
R2: 6 x 315 tests

Method

Photometric UV test with endpoint determination

Principle

Ammonium molybdate + Sulphuric acid + Phosphate

⟶ inorg. phosphorus molybdate complex

Maximum complex absorption is 340 nm.

Reagents

Components and Concentrations

R1:	Glycine/sulphuric acid buffer	50 mmol/L
R2:	Glycine buffer	50 mmol/L
	Ammonium molybdate	1.75 mmol/L

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions

1. Reagent 1: Warning. H290 May be corrosive to metals. P234 Keep only in original container. P280 Wear protective gloves/protective clothing/eye protection. P390 Absorb spillage to prevent material damage.
2. In very rare cases, samples of patients with gammopathy might give falsified results [7].
3. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
4. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent trays.

Specimen

Serum, heparin plasma or urine

Stability [1]:

in serum/plasma:	1 day	at	20 – 25°C
	4 days	at	4 – 8°C
	1 year	at	–20°C

Discard contaminated specimens. Only freeze once!

in urine:	2 days	at	20 – 25°C	at pH < 5

Discard contaminated specimens.

For collection of 24 h urine add 10 mL of 10 g/dL HCl into the collection bottle to avoid phosphate precipitations.

Calibrators and Controls

For calibration the DiaSys TruCal U calibrator is recommended. The assigned values of calibrators have been made traceable to a primary phosphorus standard (traceable to the reference material NIST-SRM 723). For internal quality control DiaSys TruLab N and P or TruLab Urine controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL
TruLab Urine Level 1	5 9170 99 10 062	20 x 5 mL
	5 9170 99 10 061	6 x 5 mL
TruLab Urine Level 2	5 9180 99 10 062	20 x 5 mL
	5 9180 99 10 061	6 x 5 mL

Performance Characteristics

All concentrations given in mg/dL (mmol/L) refer to phosphorus.

Measuring range up to 30 mg/dL (9.7 mmol/L) phosphorus (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	0.2 mg/dL (0.06 mmol/L) phosphorus
On-board stability	5 weeks
Calibration stability	2 weeks

Interferences < 10% by
Ascorbate up to 30 mg/dL
Conjugated Bilirubin up to 60 mg/dL
Unconjugated Bilirubin up to 60 mg/dL
Hemoglobin up to 1000 mg/dL
Lipemia (triglycerides) up to 1800 mg/dL
For further information on interfering substances refer to Young DS [5].

Precision (Serum/plasma)			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	2.23	4.67	7.96
Mean [mmol/L]	0.72	1.51	2.57
Coefficient of variation [%]	1.23	0.93	1.25
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	1.80	3.31	8.35
Mean [mmol/L]	0.58	1.07	2.70
Coefficient of variation [%]	1.87	1.19	1.39

Method comparison (Serum/plasma; n=100)	
Test x	Competitor Phosphate
Test y	DiaSys Phosphate FS
Slope	1.000
Intercept	0.155 mg/dL (0.05 mmol/L)
Coefficient of correlation	0.998

Precision (Urine)			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	14.3	23.4	47.4
Mean [mmol/L]	4.60	7.56	15.3
Coefficient of variation [%]	0.57	0.99	0.40
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	14.0	23.3	47.8
Mean [mmol/L]	4.52	7.51	15.4
Coefficient of variation [%]	1.29	0.64	0.66

Method comparison (Urine; n=40)	
Test x	Competitor Phosphate
Test y	DiaSys Phosphate FS
Slope	0.997
Intercept	0.526 mg/dL (0.170 mmol/L)
Coefficient of correlation	0.9993

** lowest measurable concentration which can be distinguished from zero mean + 3 SD (n=20) of an analyte free specimen

Conversion factor

Serum/plasma:
Phosphorus [mg/dL] x 0.323 = Phosphorus [mmol/L]

Urine:
Phosphorus [g/24 h] x 32.3 = Phosphorus [mmol/24 h]

Reference Range

	Phosphorus [mg/dL]	[mmol/L]
Serum [2]:		
Adults	2.6 – 4.5	0.84 – 1.45
Children / Adolescents:		
1 – 30 day(s)	3.9 – 7.7	1.25 – 2.50
1 – 12 month(s)	3.5 – 6.6	1.15 – 2.15
1 – 3 year(s)	3.1 – 6.0	1.00 – 1.95
4 – 6 years	3.3 – 5.6	1.05 – 1.80
7 – 9 years	3.0 – 5.4	0.95 – 1.75
10 – 12 years	3.2 – 5.7	1.05 – 1.85
13 – 15 years	2.9 – 5.1	0.95 – 1.65
16 – 18 years	2.7 – 4.9	0.85 – 1.60

Urine [5]:
0.4 – 1.3 g/24 h (12.9 – 42.0 mmol/24 h)

Plasma [4]
Concentrations of inorganic phosphate are about 0.2 to 0.3 mg/dL (0.06 to 0.10 mmol/L) lower in heparinized plasma than in serum.

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

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7. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45()): 1240 – 1243.

Manufacturer

IVD CE

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BioMajesty

Phosphate FS

Chemistry code 10 521

Application for serum, plasma and urine samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1
Sample vol (U)	1
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	PO3
Digits	2
M-wave L.	340
S-wave.L	658
Analy.mthd.	EPA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	1	1
Diluent method	No dil	With dil
Undil. sample vol.	0	5
Diluent volume	0	50
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999