

## Phosphate FS\*

### Order Information

#### Cat. No.

1 5211 99 10 962

#### Kit size



1890 (R1: 6 x 315, R2: 6 x 315)

### Intended Use

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

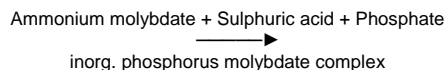
### Summary

Phosphate, an essential mineral in the human body, plays a crucial role in various physiological processes. The clinical evaluation of serum levels is vital in assessing various health conditions. Phosphate exists mainly as inorganic substance of the bones, but also in cells in phospholipids and nucleic acids as well as in adenosine triphosphate, which is involved in the energy transfer [1]. In plasma, it is present as calcium phosphate; therefore, the level of phosphate in plasma is strongly associated with the one of calcium [1]. The regulation of the phosphate level is tightly controlled by multiple factors, including the parathyroid gland, which secretes parathyroid hormone (PTH) in response to changes in serum calcium and phosphate concentrations [2]. Hyperphosphatemia, characterized by elevated serum phosphate levels, can occur in conditions such as kidney disease, where impaired renal function leads to decreased phosphate excretion. This elevation in phosphate levels can disrupt the delicate calcium-phosphate balance and is potentially leading to mineralization disorders [3]. Conversely, hypophosphatemia, a deficiency of phosphate in blood, may arise due to factors like malnutrition, vitamin D deficiency, or excessive phosphate loss from the kidneys [4]. Measuring phosphate in serum is aiding in the assessment and diagnosis of bone disorders. In addition, serum levels are indicative of renal function, can help diagnosing metabolic conditions like hyperphosphatemia or hypophosphatemia and reflect nutritional status.

### Method

Photometric UV test with endpoint determination

Phosphate ions react with ammonium molybdate under acidic conditions and form a phosphomolybdate complex. The intensity of the blue color produced is proportional to the phosphate concentration and can be measured at a wavelength of 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 and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze.

The open-vial stability of the reagent is 18 months until expiry date.

### Warnings and Precautions

- Components contained in Phosphate FS are classified according to EC regulation 1272/2008 (CLP) as follows:



⚠ Reagent 1: Warning. H290 May be corrosive to metals. P234 Keep only in original packaging. P280 Wear protective gloves/protective clothing/eye protection. P390 Absorb spillage to prevent material damage.

- In very rare cases, samples of patients with gammopathy might give falsified results [5].
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
- Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
- Please refer to the safety data sheets (SDS) 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.
- For professional use only.

### Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

### Reagent Preparation

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

### Materials Required

General laboratory equipment

### Specimen

Human serum, heparin plasma or urine

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability in serum/plasma [6]:

3 days	at	20 – 25°C
7 days	at	4 – 8°C
1 year	at	-20°C

Only freeze once. Discard contaminated specimens.

Stability in urine at pH < 5 [6]:

2 days	at	20 – 25°C
6 months	at	4 – 8°C

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

Discard contaminated specimens.

### Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to a primary phosphorus standard (traceable to the reference material NIST-SRM 723). Use DiaSys TruLab N and P or TruLab Urine Level 1 and Level 2 for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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 refer to phosphorus.

### Serum/Plasma

Measuring range up to 30 mg/dL, linearity is given within  $\pm 5\%$ . 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
Onboard stability	5 weeks
Calibration stability	2 weeks

Interference by	Interferences $\leq 10\%$ up to	Analyte concentration [mg/dL]
Ascorbic acid	30 mg/dL	3.27
Bilirubin (conjugated)	60 mg/dL	3.32
Bilirubin (unconjugated)	60 mg/dL	3.31
Hemolysis	1000 mg/dL	3.29
Lipemia (triglycerides)	1800 mg/dL	3.26

For further information on interfering substances, refer to the literature [7-9].

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	2.23	4.67	7.96
CV [%]	1.23	0.928	1.25
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	1.80	3.31	8.35
CV [%]	1.87	1.19	1.39

Method comparison (n=100)	
Test x	Competitor Phosphate (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Phosphate FS (BioMajesty® JCA-BM6010/C)
Slope	1.00
Intercept	0.155 mg/dL
Coefficient of correlation	0.998

### Urine

Measuring range up to 330 mg/dL, linearity is given within  $\pm 5\%$ . In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection**	2.2 mg/dL
Onboard stability	5 weeks
Calibration stability	2 weeks

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	14.3	23.4	47.5
CV [%]	0.566	0.992	0.399
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	14.0	23.3	47.8
CV [%]	1.29	0.644	0.663

Method comparison (n=40)	
Test x	Competitor Phosphate (BioMajesty® JCA-BM6010/C)
Test y	DiaSys Phosphate FS (BioMajesty® JCA-BM6010/C)
Slope	0.997
Intercept	0.526 mg/dL
Coefficient of correlation	0.999

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

### Conversion Factor

#### Serum/Plasma

Phosphate [mmol/L] = Phosphorus [mmol/L]

Phosphorus [mg/dL] x 0.3229 = Phosphorus [mmol/L]

Phosphorus [mg/dL] x 3.06619 = Phosphate [mg/dL]

#### Urine

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

### Reference Range

#### Serum [10]

	Phosphorus	
	[mg/dL]	[mmol/L]
<b>Adults</b>	2.6 – 4.5	0.84 – 1.45
<b>Children/Adolescents</b>		
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 years	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

#### Plasma [11]

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.

#### Urine [12]

0.4 – 1.3 g/24 h      12.9 – 42.0 mmol/24 h

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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Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.

# BioMajesty®



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\* Fluid Stable

## 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 / Urine control
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.l	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.l.	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