

Phosphate FS*

Diagnostic reagent for quantitative in vitro determination of phosphorus in serum or plasma on Sysmex BX-Series

Order information

Cat. No.	Kit size	Number of tests
1 5211 99 10 972	R1 3 x 11.6 mL	BX-3010 3 x 75 tests BX-4000 3 x 57 tests
	R2 3 x 4.8 mL	BX-3010 3 x 75 tests BX-4000 3 x 57 tests

Method

Photometric UV test with endpoint determination

Principle

Ammonium molybdate + Sulphuric acid + Phosphate



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 [6].
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 or heparin plasma

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!

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 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

Performance Characteristics

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

Measuring range up to 30 mg/dL (9.69 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	6 weeks
Calibration stability	6 weeks

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

Interfering substance	Interferences < 10%	Analyte concentration
Ascorbate	up to 30 mg/dL	3.26 mg/dL (1.05 mmol/L)
Hemoglobin	up to 1000 mg/dL	3.28 mg/dL (1.06 mmol/L)
Bilirubin, conjugated	up to 60 mg/dL	3.31 mg/dL (1.07 mmol/L)
Bilirubin, unconjugated	up to 60 mg/dL	3.30 mg/dL (1.07 mmol/L)
Lipemia (triglycerides)	up to 2000 mg/dL	4.90 mg/dL (1.58 mmol/L)
	up to 2000 mg/dL	3.19 mg/dL (1.03 mmol/L)

For further information on interfering substances refer to Young DS [5].

Precision BX-4000			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	1.60	7.75	14.3
Mean [mmol/L]	0.517	2.50	4.61
Coefficient of variation [%]	1.46	0.622	0.407
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	1.62	8.11	14.4
Mean [mmol/L]	0.522	2.62	4.65
Coefficient of variation [%]	1.95	0.721	0.854

Method comparison (n=108)	
Test x	Phosphate FS (BioMajesty 6010C)
Test y	Phosphate FS (BX-4000)
Slope	1.02
Intercept	-0.0355 mg/dL (-0.011 mmol/L)
Coefficient of correlation	0.999

Conversion factor

Serum/plasma:

$$\text{Phosphorus [mg/dL]} \times 0.323 = \text{Phosphorus [mmol/L]}$$

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

Plasma [3]

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

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 40-1.
2. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 241-7.
3. Burtis CA, Ashwood ER, Bruns DE. Tietz Textbook of Clinical Chemistry. 4th ed. Elsevier Saunders; 2006. p. 1908.
4. Endres DB, Rude RK. Mineral and bone metabolism. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1395-1457.
5. Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1829.
6. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
7. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(11): 1240 – 1243.



Manufacturer

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

Chemistry Parameters 1				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters																						
Method No.	*	Method Name	PHOS	Reagent Name	Reagent (µL)	Water (µL)																				
Print Name	Phosphate	MethodColor		R1	PHOS	120																				
Sample Type	Serum			R2	PHOS	30																				
Unit	mg/dL			Diluent	Disable																					
Assay Type	End			Sample Ppt. Wash	Disable																					
Measuring points		Start	End	Stirring Speed R1	Middle	R2 Middle																				
		1	22 - 23																							
		2	45 - 46																							
Wave Length	Prim. 340	Sec. 660		<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>No.</th> <th>Normal Range Name</th> <th>Min</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Male-G1</td> <td>*</td> <td>*</td> </tr> <tr> <td>2</td> <td>Male-G2</td> <td>*</td> <td>*</td> </tr> <tr> <td>3</td> <td>Male-G3</td> <td>*</td> <td>*</td> </tr> <tr> <td>4</td> <td>Female-G1</td> <td>*</td> <td>*</td> </tr> </tbody> </table>			No.	Normal Range Name	Min	Max	1	Male-G1	*	*	2	Male-G2	*	*	3	Male-G3	*	*	4	Female-G1	*	*
No.	Normal Range Name	Min	Max																							
1	Male-G1	*	*																							
2	Male-G2	*	*																							
3	Male-G3	*	*																							
4	Female-G1	*	*																							
Normal	Sample Volume (µL)	Diluted Sample (µL)	Diluent (µL)	Technical Range																						
	Low Normal High			(Conc)	0.2	30.0																				
<input type="checkbox"/> Diluent	0.0 < 1.5 < 0.0			(mAbs/10)	*	*																				
<input type="checkbox"/> Rerun (High/Prozone)				Previous Result Comparison (%)	*	* %																				
<input type="checkbox"/> Diluent	0.0 < 1.5 < 0.0			Abnormal Range	*	*																				
<input type="checkbox"/> Rerun (Low)				Panic Range	*	*																				
<input type="checkbox"/> Diluent	0.0 < 1.5 < 0.0			Decimal Point	1	Profile SI Disable																				

*Entered by user

Chemistry Parameters 2				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters		
Method No.	*	Method Name	PHOS	Sample	Serum	
Limit Checks <input checked="" type="checkbox"/> Duplicate Limit 50 mAbs/10 <input checked="" type="checkbox"/> Sensitivity Limit 1800 mAbs/10 <input checked="" type="checkbox"/> Linearity Limit % (mAbs/10)/min <input type="checkbox"/> Prozone Limit Higher % SL1-S - SL1-F SL2-S - SL2-F Sensitivity mAbs/10 <input checked="" type="checkbox"/> Absorbance Limit Abs. in reaction Increase Limit 25000 mAbs/10				Blank measurement Blank measurement: Disable reagent blank and C1 blank Measurement of Reagent Blank during Run: None Reagent blank measurement at calibration: Reagent blank (No sample) The number of measurement: Duplicate Reagent blank limit checks: <input checked="" type="checkbox"/> Duplicate Limit 20 mAbs/10		
				Instrument Factor a 1.00 b 0.00		

Calibration Registration

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No.

Method Name

Sample Type

Replication

Check Interval

Test without calibration

Calibration Type

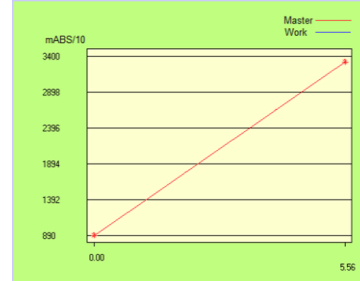
Reagent Lot

Calibrator Name

Reagent Lot No.

(R1)
(R2)

Last



The calibration curve is lot dependent

	Conc.	WORK	MASTER	Calibr. Lot No.	<input type="checkbox"/> All
C1	0	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

K C1 Blank
 Reagent Blank for C1

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10

*Entered by user

Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters					
Method	*	Name	PHOS	Reagent Name	Reagent (µL)	Water (µL)	
Print Name	Phosphate	R1	PHOS	160			
Sample	Serum	R2	PHOS	40			
Unit	mg/dL	Diluent <input type="checkbox"/> Enable					
Assay Type	End						
Measuring points		Start	End	Decimal Points	1		
	1	33	34				
<input type="checkbox"/> Enable	2	67	68				
Wave Length	Prim. 340	Sec	<input type="checkbox"/> Disable 660	Normal Range			
				No.	Normal Range Name	Min	Max
				1	Male-G1	*	*
				2	Male-G2	*	*
				3	Male-G3	*	*
				4	Female-G1	*	*
				Technical Range			
<input type="checkbox"/> Dilution	2.0	Sample (µL)		Diluent (µL)	(Conc) 0.2	30.0	
Rerun (High/Prozone)				(mAbs/10)			
<input type="checkbox"/> Dilution	2.0						
Rerun (Low)							
<input type="checkbox"/> Dilution	2.0						
				SPT Wash	<input type="checkbox"/> Enable	Reagent Name	
				Stirring Speed	R1 Middle	R2 Middle	

*Entered by user

Chemistry Parameters		Sysmex BX-4000 Chemistry Analyzer Analytical Parameters			
Method No.	*	Name	PHOS	Sample	Serum
Limit Checks					
<input checked="" type="checkbox"/> Duplicate Limit	50	mAbs/10			
<input checked="" type="checkbox"/> Sensitivity Limit	1800	mAbs/10			
<input checked="" type="checkbox"/> Linearity Limit		%		(mAbs/10)/min	
<input type="checkbox"/> Prozone Limit		%	Upper		
	SL1-S	-	SL1-F		
	SL2-S	-	SL2-F		
	Sensitivity	mAbs/10			
<input checked="" type="checkbox"/> Absorbance Limit					
	Reaction	Increase			
	Limit	25000 mAbs/10			
Blank measurement					
Blank measurement:					
Disable reagent blank and S1 blank					
Measurement of Reagent Blank during Run:					
None					
Reagent blank measurement at calibration:					
Reagent blank (No sample)					
The number of measurement:					
Duplicate					
Reagent blank limit checks:					
<input checked="" type="checkbox"/> Duplicate Limit	20	mAbs/10			
Instrument Factor					
	a	1.00	b	0.00	

Registration Calibration

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method Name

R Lot No. R1 Last
R2

Sample

Sampling

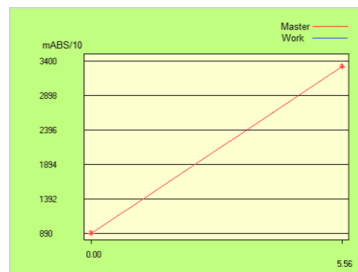
Check Interval days

Auto

Auto Interval hours

Type Lot

Material Name



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Type Conc.

Absorbance mAbs/10

	Conc.	WORK	MASTER	Lot No. (S) <input type="checkbox"/> All
S1	<input type="text" value="0"/>	Automatic entry	Automatic entry	
S2	<input type="text" value="*"/>	Automatic entry	Automatic entry	
S3	<input type="text" value="*"/>			
S4	<input type="text" value="*"/>			
S5	<input type="text" value="*"/>			
S6	<input type="text" value="*"/>			
S7	<input type="text" value="*"/>			

K S1 Blank Reagent Blank for S1

*Entered by user