respons®920

Phosphate FS*

Diagnostic reagent for quantitative in vitro determination of phosphorus in serum or plasma on DiaSys respons®920

Order Information

Cat. No. 1 5211 99 10 920
4 twin containers for 200 determinations each

Method

Photometric UV test with endpoint determination

Principle

Ammonium molybdate + Sulphuric acid + Phosphate

⟶ inorg. phosphorus molybdate complex

The complex absorption is maximal at 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. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
3. In very rare cases, samples of patients with gammopathy might give falsified results [7].
4. 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.
5. 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 rotor.

Specimen

Serum or heparin plasma

Stability [1]:

1 day	at	20 – 25°C
4 days	at	4 – 8°C
1 year	at	–20°C

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

DiaSys TruCal U calibrator is recommended for calibration. The assigned values of the calibrator have been made traceable to a primary phosphate standard (traceable to NIST-SRM 723 reference material). 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 refer to phosphorus.

Measuring range up to 30 mg/dL 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**	0.1 mg/dL phosphorus
On-board stability	4 weeks
Calibration stability	4 weeks

Interferences < 10% by
Ascorbate up to 30 mg/dL
Hemoglobin up to 1000 mg/dL
Bilirubin up to 60 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL
For further information on interfering substances refer to Young DS [2].

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	3.55	4.83	7.07
Coefficient of variation [%]	2.81	2.15	1.94
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	3.51	4.93	6.98
Coefficient of variation [%]	2.76	2.44	1.49

Method comparison (n=110)	
Test x	DiaSys Phosphate FS (Hitachi 917)
Test y	DiaSys Phosphate FS (respons®920)
Slope	1.00
Intercept	0.06 mg/dL
Coefficient of correlation	0.993

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

Conversion factor

Phosphate [mmol/L] = Phosphorus [mmol/L]
Phosphorus [mg/dL] x 0.3229 = Phosphorus [mmol/L]
Phosphorus [mg/dL] x 3.06619 = Phosphate [mg/dL]

Reference Range

Serum [3]	**Phosphorus**	
	[mg/dL]	[mmol/L]
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 [5]

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. 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.
3. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 241-7.
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, Bruns DE. Tietz Textbook of Clinical Chemistry. 4th ed. Elsevier Saunders; 2006. p. 1908.
6. Burtis CA, Ashwood ER, Bruns DE. Tietz Textbook of Clinical Chemistry. 4th ed. Elsevier Saunders; 2006. p. 2290.
7. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007;45(9):1240–1243.

Manufacturer

IVD CE

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* fluid stable

respons®920

Phosphate FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	PO3				Auto Rerun		☐
Report Name	:	Phosphate				Online Calibration		☐
Unit	:	mg/dL	Decimal Places	:	2	Cuvette Wash		☐
Wavelength-Primary	:	340	Secondary	:		Total Reagents	:	2
Assay Type	:	2-Point	Curve Type	:	Linear	Reagent R1	:	PO3 R1
M1 Start	:	15	M1 End	:	15	Reagent R2	:	PO3 R2
M2 Start	:	33	M2 End	:	33			
Sample Replicates	:	1	Standard Replicates	:	3	Consumables/Calibrators:		
Control Replicates	:	1	Control Interval	:	0	Blank/Level 0	:	0
Reaction Direction	:	Increasing	React. Abs. Limit	:	0.00	Calibrator 1	:	*
Prozone Limit %	:	0	Prozone Check	:	Lower			
Linearity Limit %	:	0	Delta Abs./Min.	:	0.00			
Technical Minimum	:	0.10	Technical Maximum	:	30.00			
Y = aX + b a=	:	1.00	b=	:	0.00			

* Enter calibrator value.

Test Details			Test Volumes			Reference Ranges
Test	:	PO3				
Sample Type	:	Serum				

Sample Volumes

Normal	:	2.00 µL	Dilution Ratio	:	1 X	
Increase	:	4.00 µL	Dilution Ratio	:	1 X	
Decrease	:	2.00 µL	Dilution Ratio	:	2 X	
Standard Volume	:	2.00 µL				

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	180 µL	R1 Stirrer Speed	:	Medium
RGT-2 Volume	:	45 µL	R2 Stirrer Speed	:	High

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	PO3		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (mg/dL)	Upper Limit (mg/dL)
Normal	:	2.60	4.50
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other