respons®910

Phosphate FS*

Diagnostic reagent for quantitative in vitro determination of phosphorus in serum or plasma on DiaSys respons®910

Order Information

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

Method

Photometric UV test with endpoint determination

Principle

Ammonium molybdate + Sulphuric acid + Phosphate

⟶ inorg. phosphorus molybdate complex

Absorption maximum of the complex is 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/face protection. P390 Absorb spillage to prevent material damage.
2. In very rare cases, samples of patients with gammopathy might give falsified results [7].
3. To avoid contamination and carryover, special care should be taken in combination with Rheumatoid factor FS reagent.
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 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). DiaSys TruLab N and P should be assayed for internal quality control. 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**	0.2 mg/dL phosphorus
On-board stability	3 weeks
Calibration stability	7 days

Interfering substance	Interferences < 10%	Phosphorus [mg/dL]
Ascorbate	up to 30 mg/dL	2.02
Hemoglobin	up to 450 mg/dL	2.69
	up to 900 mg/dL	6.14
Bilirubin, conjugated	up to 60 mg/dL	3.12
	up to 70 mg/dL	6.94
Bilirubin, unconjugated	up to 80 mg/dL	3.11
	up to 80 mg/dL	7.04
Lipemia (triglycerides)	up to 900 mg/dL	3.32
	up to 1000 mg/dL	7.34
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]	2.00	3.55	8.79
Coefficient of variation [%]	2.32	2.08	1.39
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	2.23	3.56	8.02
Coefficient of variation [%]	1.50	1.74	2.44

Method comparison (n=131)	
Test x	DiaSys Phosphate FS (Hitachi 911)
Test y	DiaSys Phosphate FS (respons®910)
Slope	1.008
Intercept	–0.058 mg/dL
Coefficient of correlation	0.999

** according to NCCLS document EP17-A, vol. 24, no. 34

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 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(()): 1240 – 1243.

Manufacturer

IVD CE

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respons®910

Phosphate FS

Application for serum and plasma 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

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	PO3
Shortcut:	
Reagent barcode reference:	049
Host reference:	

Technic	
Type:	End point
First reagent:[µL]	180
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	45
Blank reagent	Yes
Sensitive to light	
Main wavelength:[nm]	340
Secondary wavelength:[nm]	660
Polychromatic factor:	1.000
1 st reading time [min:sec]	(04:24)
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics	
Endpoint	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	0.2
Concentration technical limits-Upper	30
SERUM	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume [µL]	6
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6
URIN	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume [µL]	6
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume [µL]	6
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume[µL]	6
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume[µL]	6
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6

Results	
Decimals	2
Units	mg/dL
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Gender	All
Age	
SERUM	>=2.6 <=4.5
URINE	
PLASMA	>=2.6 <=4.5
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
	Max delta abs.
Cal. 1	0.003
Cal. 2	0.015
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8
Calculations	
Model	X
Degree	1

* Enter calibrator value