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

Absorption maximum of the complex is at 340 nm.

Reagents

<table>
<thead>
<tr>
<th>Components and Concentrations</th>
<th>R1:</th>
<th>50 mmol/L</th>
<th>R2:</th>
<th>50 mmol/L</th>
<th>Ammonium molybdate</th>
<th>1.75 mmol/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycine/sulphuric acid buffer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glycine buffer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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. P330 Absorb spillage to prevent material damage.
2. In very rare cases, samples of patients with gammopathy might give falsified results
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.

<table>
<thead>
<tr>
<th>Serum or heparin plasma</th>
<th>Stability [1]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 day at 20 – 25°C</td>
<td></td>
</tr>
<tr>
<td>4 days at 4 – 8°C</td>
<td></td>
</tr>
<tr>
<td>1 year at 20°C</td>
<td></td>
</tr>
</tbody>
</table>

Performance Characteristics
All concentrations given in mg/dL refer to phosphorus.

<table>
<thead>
<tr>
<th>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).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limit of detection</td>
</tr>
<tr>
<td>On-board stability</td>
</tr>
<tr>
<td>Calibration stability</td>
</tr>
</tbody>
</table>

Interfering substance

<table>
<thead>
<tr>
<th>Interference</th>
<th>Interferences &lt; 10%</th>
<th>Phosphorus [mg/dL]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascorbate</td>
<td>up to 30 mg/dL</td>
<td>2.02</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>up to 450 mg/dL</td>
<td>2.69</td>
</tr>
<tr>
<td>Bilirubin, conjugated</td>
<td>up to 900 mg/dL</td>
<td>6.14</td>
</tr>
<tr>
<td>Bilirubin, unconjugated</td>
<td>up to 60 mg/dL</td>
<td>3.12</td>
</tr>
<tr>
<td>Lipemia (triglycerides)</td>
<td>up to 70 mg/dL</td>
<td>6.94</td>
</tr>
<tr>
<td>Lipemia (triglycerides)</td>
<td>up to 80 mg/dL</td>
<td>3.11</td>
</tr>
<tr>
<td>Lipemia (triglycerides)</td>
<td>up to 900 mg/dL</td>
<td>7.04</td>
</tr>
<tr>
<td>Lipemia (triglycerides)</td>
<td>up to 1000 mg/dL</td>
<td>7.34</td>
</tr>
</tbody>
</table>

For further information on interfering substances refer to Young DS [2].

Precision

<table>
<thead>
<tr>
<th>Precision</th>
<th>Within run (n=20)</th>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [mg/dL]</td>
<td>2.00</td>
<td>3.55</td>
<td>8.79</td>
<td></td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>2.32</td>
<td>2.08</td>
<td>1.36</td>
<td></td>
</tr>
</tbody>
</table>

<table>
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<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [mg/dL]</td>
<td>2.23</td>
<td>3.96</td>
<td>8.02</td>
<td></td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>1.50</td>
<td>1.74</td>
<td>2.44</td>
<td></td>
</tr>
</tbody>
</table>

Method comparison (n=131)

<table>
<thead>
<tr>
<th>Test x</th>
<th>DiaSys Phosphate FS (Hitachi 911)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test y</td>
<td>DiaSys Phosphate FS (respons®910)</td>
</tr>
</tbody>
</table>

| Slope | 1.008 |
| Intercept | –0.058 mg/dL |
| Coefficient of correlation | 0.999 |

Conversion factor

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

Reference Range

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

Plasma [5]

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

Literature

Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9
65558 Holzheim
Germany
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
1st 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
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