**PHOSPHORUS**

*In vitro diagnostic reagent, for professional use only*

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**CLINICAL SIGNIFICANCE** (1)

The main part of phosphorus of the human body (80 to 85%) is located in bones. The remaining phosphorus is mainly inorganic phosphate.

Usually, there is a relationship between calcium and phosphate in human serum. An increase of one of these components usually leads to a decrease of the other component. An elevation of serum phosphate can occur in vitamin D intoxication, hypoparathyroidism and renal failure. A decrease of serum phosphate is bound to vitamin D deficiency and hyperparathyroidism.

**METHOD**

Phosphomolybdate.

U.V. End point.

**PRINCIPLE** (2)

Determination of inorganic phosphorus is made according to the following reaction:

\[ \text{Phosphorus} + \text{Ammonium molybdate} + \text{Sulfuric acid} \rightarrow \text{Phosphomolybdate complex} \]

**REAGENT COMPOSITION**

**Reagent: R**

Sulfuric acid 210 mmol/L

Ammonium molybdate 650 µmol/L

**Standard: Std**

Phosphorus 5 mg/dL

50 mg/L

1.62 mmol/L

**MAERIAL REQUIRED BUT NOT PROVIDED**

CONT-0060 ELITROL I 10 × 5 mL

CONT-0160 ELITROL II 10 × 5 mL

**PRECAUTIONS**

- The reagent contains sulfuric acid. It is irritant (Xi).

R36/38 : Irritating to eyes and skin.

S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S37/39 : Wear suitable gloves and eye/face protection.

- Use clean or single use laboratory equipment to avoid contaminations.

- The standard should be immediately and tightly capped to prevent contamination and evaporation.

**WASTE MANAGEMENT**

Disposal of all waste material should be in accordance with local and legal requirements.

**STABILITY OF REAGENTS**

To store at 2-25°C and protected from light.

The reagent and the standard are stable until the expiry date stated on the label.

**ON-BOARD STABILITY**

The stability is specific for each analyser (for Selectra refer to § PERFORMANCE DATA)

**PREPARATION AND STABILITY OF WORKING REAGENT**

The reagent and the standard are ready to use.

**SAMPLES** (3,4)

- Specimen

Serum free of hemolysis from fasting patient.

Heparinized plasma.

**Urine to acidify (pH<3) after collection and to dilute at 1/10 with distilled water before analysis (when there is no predilution by the analyser).**

**- Storage**

Acidified urines are stable for 6 months.

Plasma and serum are stable at 4°C for 1 week, frozen for several months.

**REFERENCE VALUES** (1)

Serum: 2.7 - 4.5 mg/dL

27 - 45 mg/L

0.87 - 1.45 mmol/L

Urine: 400 - 1300 mg/24h

12.9 - 42.0 mmol/24h

**Note**: It is recommended for each laboratory to establish and maintain its own reference values. The data given here are only an indication.

**PROCEDURE**

This reagent can be used on most analysers, semi automated analysers and manual methods.

The applications are available on request.

Wavelength : 340 nm

Temperature : 37°C

Read against reagent blank.

**BLANK CALIBRATION TEST**

<table>
<thead>
<tr>
<th>Reagent R</th>
<th>BLANK</th>
<th>CALIBRATION</th>
<th>TEST</th>
</tr>
</thead>
<tbody>
<tr>
<td>300 µL</td>
<td>300 µL</td>
<td>-</td>
<td>300 µL</td>
</tr>
<tr>
<td>Distilled water</td>
<td>3 µL</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Standard</td>
<td>-</td>
<td>3 µL</td>
<td>-</td>
</tr>
<tr>
<td>Sample</td>
<td>-</td>
<td>-</td>
<td>3 µL</td>
</tr>
</tbody>
</table>

Mix and read the absorbance (A) after a 100 second incubation.

**CALCULATION**

\[ A_{\text{Sample}} \times n = \text{standard concentration} \]

\[ A_{\text{Standard}} \]

Take dilution factor into account for the calculation of phosphorus concentration in urine.

**CALIBRATION**

Phosphorus standard is traceable to the Standard Reference Material SRM 186lg.

The calibration frequency is specific for each analyser (for Selectra refer to § PERFORMANCE DATA).

**QUALITY CONTROL**

To ensure adequate quality, control sera such as ELITROL I (normal control) and ELITROL II (abnormal control) are recommended.

**PERFORMANCE DATA at 37°C on Selectra**

- **Analytical range**

The reagent is linear from 2 to 20 mg/dL (20 to 200 mg/L), (0.65 to 6.5 mmol/L).

- **Detection limit** (5)

Determined according to SFBC protocol, the detection limit is equal to 0.84 mg/dL (8.4 mg/L), (0.27 mmol/L).

- **Analytical Sensitivity**

The average variation of the analytical signal is \(49 \times 10^{-3} \Delta A\) per mg/dL of phosphorus (or \(4.9 \times 10^{-3} \Delta A\) per mg/L, 0.152 \(\Delta A\) per mmol/L) for a light path of 1 cm.
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- Precision

Within-run reproducibility

<table>
<thead>
<tr>
<th></th>
<th>Normal serum:</th>
<th>Abnormal serum:</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>m (mg/dL)</td>
<td>4.12</td>
<td>7.99</td>
</tr>
<tr>
<td>CV%</td>
<td>1.6</td>
<td>2.2</td>
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</tbody>
</table>

Between-run reproducibility

<table>
<thead>
<tr>
<th></th>
<th>Normal serum:</th>
<th>Abnormal serum:</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>19</td>
<td>20</td>
</tr>
<tr>
<td>m (mg/dL)</td>
<td>4.46</td>
<td>8.71</td>
</tr>
<tr>
<td>CV%</td>
<td>2.8</td>
<td>2.3</td>
</tr>
</tbody>
</table>

- Correlation

A comparative study has been performed between Elitech method and another commercial reagent (phosphomolybdate-uv method) on 36 human serum samples. Sample concentrations were between 1.85 and 26.1 mg/dL.

The parameters of linear regression are as follows:

Correlation coefficient: \( r = 0.9993 \)

Linear regression: \( y = 1.0540 x - 0.327 \) mg/dL

- Interferences (5)

According to SFBC recommendations, some studies have been performed to determine the level of interference from different compounds:

- Unconjugated Bilirubin: Positive bias from 12 mg/dL of bilirubin (120 mg/L, 205 µmol/L)
- Conjugated bilirubin: No significant interference up to 21 mg/dL (210 mg/L, 360 µmol/L)
- Ascorbic Acid: No significant interference up to 20 mg/dL (200 mg/L, 1.1 mmol/L)
- Haemoglobin: Positive bias from 150 mg/dL (1.5 g/L)
- Glucose: No significant interference up to 550 mg/dL (5.5 g/L, 29.7 mmol/L)
- Turbidity: Positive bias from 250 mg/dL Triglyceride equivalent (2.5 g/L, 2.87 mmol/L)
- Calcium: No significant interference up to 100 mg/dL (1 g/L, 25 mmol/L)
- Magnesium: No significant interference up to 10 mg/dL (100 mg/L, 4.12 mmol/L)
- Iron: No significant interference up to 1 mg/dL (10 mg/L, 0.18 mmol/L)

Other compounds may interfere (6-8)

- On board stability on SELECTRA (not refrigered)

On-board stability: 14 days (copped vials and stored at 2-25 °C during the night)

Calibration frequency: 7 days

Make anew calibration when reagent lots change, when quality control results fall outside the established range, and after a maintenance operation.

BIBLIOGRAPHY


SYMBOLS USED ON LABELS

- IVD: In vitro diagnostic medical device
- REF: Manufacturer’s address
- LOT: Expiration date
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