INTENDED USE

The TRUEchemie Inorganic Phosphorus reagent test for the quantitative determination of Inorganic Phosphorus in serum or urine.

INTRODUCTION

Inorganic Phosphorus is present in a small but significant amount, mainly as phosphate ions. The metabolism of phosphorus and calcium are closely related. Decreased levels of serum phosphorus are associated with conditions like primary hyperparathyroidism, osteomalacia, rickets, etc. Elevated levels of serum phosphorus are associated with hypoparathyroidism and Paget’s disease, vitamin-D intoxication and chronic nephritis. Elevated urinary phosphorus excretion is observed in hyperparathyroidism while decreased excretion is observed in rickets, mainly due to its impaired absorption.

Phosphorus levels are estimated either directly at 340 nm, after reaction with molybdate or by reducing phosphomolybdate to blue coloured complex using various reducing agents. Unlike older methods, our method does not involve deproteinization of the specimen. Inorganic Phosphorus reads with ammonium molybdate in strong acidic medium to form phospho-inorganic molybdate Complex. The absorbance of this complex is directly proportional to the Phosphorus concentration.

PRINCIPLE

Inorganic Phosphorus reads with ammonium molybdate in strong acidic medium to form phospho-inorganic molybdate Complex. The absorbance of this complex is directly proportional to the Phosphorus concentration.

Phosphorus + Ammonium Molybdate → Phospho-Inorganic Molybdate Complex

PACK SIZE

<table>
<thead>
<tr>
<th>Kit Size</th>
<th>1 x 50 ml</th>
<th>2 x 50 ml</th>
<th>25 T</th>
<th>50 T</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cat. No.</td>
<td>ADX421</td>
<td>ADX422</td>
<td>ADX424</td>
<td>ADX425</td>
</tr>
<tr>
<td>Kit Contents</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1) Phosphorus reagent</td>
<td>1 x 50 ml</td>
<td>2 x 50 ml</td>
<td>25 T</td>
<td>50 T</td>
</tr>
<tr>
<td>2) Phosphorus standard (5 mg/dl)</td>
<td>1 x 2 ml</td>
<td>1 x 2 ml</td>
<td>1 x 2 ml</td>
<td>1 x 2 ml</td>
</tr>
</tbody>
</table>

STORAGE AND STABILITY

The components of the kit, stored at +15 - +30 °C or room temperature, will remain stable until the expiry date stated on the label.

REAGENT PREPARATION

Ready to use reagents.

SAMPLE / SPECIMEN AND STORAGE

Unhemolysed Serum

MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipettes to accurately measure required volumes.
2. Disposable test tubes
3. Timer
4. Photometer capable of accurately measuring absorbance at 340 nm.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use.
2. Specimens should be considered infectious and handled appropriately.
3. Avoid ingestion. DO NOT PIPETTE BY MOUTH.
4. Essential precautions must be taken against accidental contamination. Use only disposable material (test tubes, micro tips etc.)
5. Contamination of glassware will adversely affect the phosphorus test results.
6. Contamination free disposable plastic tubes are only recommended to perform the phosphorus assay.
7. The disposal of the residues has to be done as per local legal regulations.

TEST PROCEDURE

Wavelength : 340 nm

<table>
<thead>
<tr>
<th></th>
<th>Blank (ml)</th>
<th>Standard (ml)</th>
<th>Sample (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phosphorus Reagent</td>
<td>1.000</td>
<td>1.000</td>
<td>1.000</td>
</tr>
<tr>
<td>Phosphorus Standard</td>
<td>0.010</td>
<td></td>
<td>0.010</td>
</tr>
</tbody>
</table>

Incubate all tubes at Room Temperature for 10 minutes. After incubation, zero the photometer with the reagent blank at 340 nm. Read and record the incubated standards and samples.

Calculation = ----------------------------- x 5 mg Phosphorus/dl

QUALITY CONTROLS

Control Sera are recommended to monitor the performance of manual and automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

NORMAL VALUES

<table>
<thead>
<tr>
<th>Sample</th>
<th>Men</th>
<th>Women</th>
<th>Children</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>2.1 - 5.6 mg/dl</td>
<td>1.6 - 6.8 mg/dl</td>
<td>4.0 - 7.0 mg/dl</td>
</tr>
<tr>
<td>Urine</td>
<td>0.3 - 1.30 g/24 hours or 9.8 - 32 mmol/day</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

It is strongly recommended that each laboratory establish its own normal range.

AUTOMATED PROCEDURE

Appropriate program sheet is available for different analyzers upon request.

CALIBRATION

The procedures are calibrated with the standard solution which is included with each series of tests. Its absorbance is used to calculate the results.

LIMITATIONS OF TEST

1. Linearity : upto 20 mg/dl.
2. Sensitivity : upto 0.6 mg/dl.
3. Samples that have phosphorus values greater than 20 mg/dl should be diluted with saline water (NaCl 0.9 %) 1:1, re-assayed and the results multiplied by 2.

INTERFERENCES

1. Bilirubin can result in falsely depressed Phosphorus levels.
2. Hemoglobin samples may cause falsely elevated Phosphorus levels.

SYSTEM PARAMETERS

<table>
<thead>
<tr>
<th>Mode</th>
<th>End point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Std. Conc.</td>
<td>5</td>
</tr>
<tr>
<td>Wave length</td>
<td>340 nm</td>
</tr>
<tr>
<td>Flow cell Temp.</td>
<td>37 °C</td>
</tr>
<tr>
<td>Blank</td>
<td>Reagent</td>
</tr>
<tr>
<td>Reagent volume</td>
<td>1.000 ml</td>
</tr>
<tr>
<td>Sample volume</td>
<td>0.010 ml</td>
</tr>
<tr>
<td>Incubation</td>
<td>10 min. at R.T.</td>
</tr>
<tr>
<td>Low Normal</td>
<td>1.6</td>
</tr>
<tr>
<td>High Normal</td>
<td>7.0</td>
</tr>
<tr>
<td>Linearity</td>
<td>20</td>
</tr>
</tbody>
</table>

REFERENCES

2. Daly, J.A. Clin Chem. 18:263, 1972

Index of Symbols

- Consult instructions for use
- For in vitro diagnostic use only
- Use-by date
- Do not use if package is damaged
- Keep away from sunlight
- Manufacturer
- European Conformity
- Authorized Representative