ISE S.r.l. **Phosphorus** – Instructions for use

CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

CE IVD

R1: 4x 17,5 mL **R3330000023** REF

Diagnostic reagent for quantitative in vitro determination of phosphorus in human serum, plasma or urine on photometric systems.

## TEST PARAMETERS

| | |
|---|---|
| Method: | UV, Endpoint, Increasing reaction, Phosphomolybdate |
| Wavelength: | 340 nm, Hg 334 nm, Hg 365 nm |
| Temperature: | 20 – 25 °C, 37 °C |
| Sample: | Serum, heparin plasma, urine |
| Linearity: | up to 15 mg/dL (4.84 mmol/L) |
| Sensitivity: | The lower limit of detection is 0.7 mg/dL (0.23 mmol/L). |

## SUMMARY [1,2]

Phosphorus exists in the body almost exclusively as phosphate, mainly as inorganic substance of the bones, but also in cells in phospholipids and nucleic acids as well as in adenosine triphosphate, which is involved in the energy transfer. In plasma it is present as calcium phosphate; therefore, in level of plasma phosphorus is strongly associated with that of calcium levels. Measurement of phosphorus in serum and urine is mainly performed to detect disorders of kidneys, bones and parathyroid glands. Increased concentrations are found in renal failure, hypoparathyroidism, pseudo-hyperparathyroidism and vitamin D deficiency. Additional information can be obtained by supplementary measurement of calcium.

## TEST PRINCIPLE

In sulfuric acid solution phosphate reacts with ammonium molybdate to form a yellow phosphorus molybdate complex Maximum complex absorption is at 340 nm. It is proportional to the concentration of inorganic phosphate in the sample.

## REAGENT COMPOSITION

| COMPONENTS: | CONCENTRATION |
|---|---|
| Ammonium Molybdate | 0.4 mmol/L |
| Sulphuric acid | 180 mmol/L |

## REAGENT PREPARATION

The reagent is ready to use.

## STABILITY AND STORAGE

| | |
|---|---|
| Conditions: | Protect from light.<br>Close immediately after use.<br>Do not freeze the reagent.<br>Avoid contamination. |
| Storage: | at 2 – 25°C |
| Stability: | up to the expiration date |

## SAMPLE PREPARATION

**Urine:** For collection of 24 h urine add 10 ml of 10 g/dL HCl into the collection bottle to avoid phosphate precipitations.
Dilute urine 1 + 10 with dist water before determination and multiply the result by 11.

## SAMPLE STABILITY AND STORAGE [4]

| | | |
|---|---|---|
| Stability: | | |
| in serum / heparin plasma: | at 20 – 25 °C | 1 day |
| | at 4 – 8 °C | 4 days |
| | at -20 °C | 1 year |
| in urine (pH <5): | at 20 – 25 °C | 2 days |

Discard contaminated specimens. Freeze only once!

## MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution (9 g/L)
General laboratory equipment

## STANDARD

(not included in the kit – has to be ordered separately)

| | |
|---|---|
| Concentration: | 5 mg/dL (1.61 mmol/L) |
| Storage: | 2 – 25 °C |
| Stability: | up to the expiration date |

Close immediately after use! Avoid contamination!

## MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

| Pipette into test tubes | Blank | Std./Cal. | Sample |
|---|---|---|---|
| Reagent | 1000 µL | 1000 µl | 1000 µL |
| distilled water | 10 µL | - | - |
| Standard/Calibrator | - | 10 µL | - |
| Sample | - | - | 10 µL |
| Mix incubate for 5 min. at 20 – 25 °C / 37 °C . Measure absorbance of std./cal. and sample against reagent blank within 60 minutes. | | | |

## CALCULATION

Serum/Plasma:

$$\text{Phosph. [mg/dL]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std/Cal}} \times \text{Conc. Std/Cal [mg/dl]}$$

Urine:

$$\text{Phosph. [mg/dL]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std/Cal}} \times \text{Conc. Std/Cal [mg/dL]} \times 11$$

## UNIT CONVERSION

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

## REFERENCE RANGE *

**Serum** [1]:

| **Children** | mg/dL | mmol/L |
|---|---|---|
| 1 – 30 days | 3.9 - 7.7 | 1.25 – 2.50 |
| 1 – 12 months | 3.5 – 6.6 | 1.15 – 2.15 |
| 1 – 3 years | 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 |
| **Adults** | 2.6 – 4.5 | 0.84 – 1.45 |

| | | |
|---|---|---|
| **Urine** [3]: | 0.4 – 1.3 g/24h | 12.9 – 42.0 mmol/24h |

Plasma **[3]**:

Concentrations of inorganic phosphate are about 0.2 to 0.3 mg/dL (0.06-0.10 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.

## PERFORMANCE CHARACTERISTICS

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***Linearity, MEASURING RANGE***

The test has been developed to determine phosphorus concentrations within a measuring range from 0.7 – 15 mg/dL (0.23 – 4.84 mmol/L).
When values exceed this range, samples should be diluted 1 + 1 with NaCl (9 g/L sodium chloride in water) and the results multiplied by 2.

**SENSITIVITY/LIMIT OF DETECTION**

The lower limit of detection is 0.7 mg/dL (0.23 mmol/L)

PRECISION (at 37°C)

| Intra-assay n = 20 | Mean [mg/dL] | SD [mg/dL] | CV [%] |
|---|---|---|---|
| Sample 1 | 4.42 | 0.08 | 1.87 |
| Sample 2 | 8.43 | 0.07 | 0.85 |
| Sample 3 | 10.8 | 0.13 | 1.20 |

| Inter-assay n = 20 | Mean [mg/dL] | SD [mg/dL] | CV [%] |
|---|---|---|---|
| Sample 1 | 4.34 | 0.13 | 2.99 |
| Sample 2 | 8.20 | 0.27 | 3.32 |
| Sample 3 | 10.6 | 0.31 | 2.95 |

**SPECIFICITY/INTERFERENCES**

no interference up to:

| | |
|---|---|
| ascorbic acid | 30 mg/dL |
| bilirubin | 20 mg/dL |
| hemoglobin | 150 mg/dL |
| triglycerides | 800 mg/dL |

For further information on interfering substances refer to Young DS (6).

## METHOD COMPARISON

A comparison between our Phosphorus (y) and a commercially available test (x) using 59 samples gave following results: y = 1.00x – 0.14 mg/dl; r = 0.999.

**CALIBRATION**

The assay requires the use of a Phosphorus Standard or a Calibrator.

**QUALITY CONTROL**

All control sera with Phosphorus values determined by this method can be used.
Each laboratory should establish corrective action in case of deviations in control recovery.

**AUTOMATION**

Special applications for automated analyzers can be made on request.

**WARNINGS AND PRECAUTIONS**

1. Reagent: 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. In very rare cases, samples of patients with gammopathy might give falsified results [6].
3. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
4. 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.

**REFERENCES**

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5. Guder WG, Zatwa B et al. The quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag, 2001: 40-1, 52-3.
6. 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.
7. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007; 45(9): 1240-1243.

**Symbols on labels and packaging**

IVD = In vitro diagnostic medical device

REF = Catalog Number

LOT = Lot Number

= Manufacturer

= Expiration date

= Temperature limitation

= Instruction for use

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