TRUEchemie Phosphorus (Inorganic) Test Kit (Ammonium molybdate)

for the quantitative determination of Inorganic Phosphorus in serum or urine

INTENDED USE

The TRUEchemie Phosphorus (Inorganic) Test Kit (Ammonium molybdate) is used 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.

PRINCIPLE

Inorganic Phosphorus reacts 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 —(Acidic Medium)→ **Phospho-Inorganic Molybdate Complex**

PACK SIZE

Kit Size	2 x 50 ml	50 T
Cat. No.	ADX422	ADX425
Kit Contents		
1) Inorganic Phosphorus Reagent	2 x 50 ml	50 x 1 ml
2) Inorganic Phosphorus Standard (5 mg/dL)	1 x 2 ml	1 x 2 ml

REAGENT COMPOSITION

1) Inorganic Phosphorus Reagent

Ammonium molybdate	: 0.6 mmol/L
Sulphuric acid	: 0.3 %
Polyvinyl pyrrolidone	: 0.25 mmol/L
Dimethyl formamide	: 0.4 mmol/L
Stabilizers, Surfactants and inactive ingredients	
2) Inorganic Phosphorus Standard	: 5 mg/dL

REAGENT PREPARATION

Ready to use reagents.

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.

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.

REAGENT STORAGE & STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 15-30ºC and contaminations are prevented during their use. Do not use reagents over the expiration date.

SPECIMEN COLLECTION AND STORAGE

Serum samples are stable 8 hours when stored at room temperature (15 - 25°C) or more than one week when stored at 2-8°C. Urine may contain larger quantities of organic phosphates, which can decompose on exposure to elevated temperatures. When acidified with HCl, urine phosphate is stable for more than 6 months.

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.

TEST PROCEDURE

Wavelength : 340 nm

	Blank (µl)	Standard (µl)	Sample (µl)
Inorganic Phosphorus Reagent	1000	1000	1000
Inorganic Phosphorus Standard	--	10	--
Sample	--	--	10

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.

$$\text{Calculation} = \frac{\text{Sample OD}}{\text{Standard OD}} \times 5 \text{ mg Phosphorus/dL}$$

QUALITY CONTROL

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

EXPECTED VALUE

Serum

Men	:	2.1 - 5.6 mg/dL
Women	:	1.6 - 6.8 mg/dL
Children	:	4.0 - 7.0 mg/dL

Urine : 0.3 - 1.30 g/24 hours or 9.6 - 32 mmol/day

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

PERFORMANCE CHARACTERISTICS

Sensitivity: upto 0.56 mg/dL

Linearity: upto 20 mg/dL under the described assay conditions. If the concentration is greater than linearity (20 mg/dL), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor. The linearity limit depends on the sample / reagent ratio, as well as the analyzers used.

PRECISION:

Intra-assay precision within run (n=10)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Control Level - 1	4.03	0.04	1.03
Control Level - 2	7.05	0.04	0.53

Inter-assay precision run to run (n=12)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Control Level - 1	4.05	0.05	1.21
Control Level - 2	7.03	0.06	0.81

The reagent was tested for 12 days, using two different Inorganic Phosphorus concentrations. The coefficient of variation was <5%.

AUTOMATED PROCEDURE

Appropriate program sheet is available for different analyzers upon request.

METHOD COMPARISON

Results obtained using TRUEchemie Inorganic Phosphorus reagent (y) did not show systematic differences when compared with another commercial reagent (x) with similar characteristics. The results obtained is below: The correlation coefficient (r^2) was 0.959 and the regression equation is y=1.058x-0.152. The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

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

WASTE MANAGEMENT

Please refer to local regulation requirements.

SYSTEM PARAMETERS

Mode	:	End point
Std. Conc.	:	5
Wave length	:	340 nm
Units	:	mg/dL
Flow cell Temp.	:	37 °C
Blank	:	Reagent
Reagent volume	:	1000 µl
Sample volume	:	10 µl
Incubation	:	10 min. at R.T.
Low Normal	:	1.6
High Normal	:	7.0
Sensitivity	:	0.56
Linearity	:	20
Reaction Slope	:	Increasing

REFERENCES

1. Gindler E.M. (1969) Clin.Chem 15, 807
2. Daly, J.A. Clin Chem. 18:263, 1972
3. Morin L.G. (1973) Clin.Chem.Acta 46,113
4. Gamst, O and Try, K, Scand. J.Clin.Lab. Invest.40, 1980
5. ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

Index of Symbols

Consult instructions for use	REF Catalogue number	Caution
IVD *In vitro* diagnostic medical device	LOT Batch code	Non-sterile
15°C 30°C Temperature limit 15-30°C	Do not re-use	Use-by date
Manufacturer	Date of manufacture	Keep dry
		Keep away from sunlight

Do not use if package is damaged — Contains sufficient for <n> tests

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