ANA BIO ISP PHOSPHORUS

(UV-End Point Method)

For Miura Instruments

Intended Use

Phosphorus is a reagent kit used for the quantitative determination of Inorganic phosphorus in serum based on UV - End Point method using Ammonium molybdate. The reagents are for *in-vitro* diagnostic use.

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 —(Acid pH)→ Phospho-Inorganic Molybdate complex

Components & Concentration of Reagents

Reagent	Component	Concentration
Reagent	Ammonium Molybdate	0.4 mmol/L
	Sulphuric Acid	208 mmol/L
	Stabilizers, excipients & surface active agents	

Reagent storage and stability

Molybdate reagent and standard are stable till the expiry date stated on the container label.

Reagent Preparation

Liquid reagent ready for use. After opening the reagent is stable for 30 days if closed, stored at 2° - 8°C, and protect from direct light and contamination. Do not mix different batches.

Specimen collection and preservation

Blood should be collected in clean dry container. Neatly separated serum should be used. Plasma is not recommended as anticoagulants may cause false low results.
Phosphorus is stable for 7 days in neatly separated serum. If the estimation is not possible within 7 days then the specimen should be preserved at -10°C and should be used within 3 weeks.

Automation

This kit, though developed and manufactured to be used as manual assay and with I.S.E. Miura Analyzer, can be used also with other analyzers able to meet the specifications indicated in section "Reaction conditions – Test procedure" Application sheets are available for automatic instruments.
All applications not explicitly approved by KDPL. Cannot be guaranteed in terms of performance, and must there be established by the operator.

Calibration

For Calibration use the "Multicalibrator"

Calibration Stability

For the instrumentation series Miura, the calibration is recommended to be done every 10 days.

Materials required but not supplied in the kit

Calibrators and controls

Assay guidelines for Analyzer I.S.E. Miura

Analyte Name	Phosphorus	
Method Code	PHO	
Type	End-Point	
Unit	mg/dl	
Filter F1	340 nm	
Blank in	Used	
Step	Reaction Volume	U.M.
Volume reagent R1	200	µl
Sample Volume	2	µl
Final Incubation	300	Sec.

Normal range

Adults : 2.5 - 5.0 mg/dL
Children : 4.0 - 7.0 mg/dL
Note: Expected range varies from population to population and each laboratory should establish its own normal range.

Limitation

The reagent is linear up to 20 mg / dl. For higher value, dilute sample with normal saline and perform the assay. Multiply the final result by dilution factor to get the real value.

Quality Control

To ensure adequate quality control, it is recommended that each batch should include a normal and an abnormal commercial reference control serum. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glassware, Wavelength setting, Expiration date of reagents and accuracy of prob aspiration.

Accuracy-Recovery

Phosphorus added to a serum matrix containing known amounts of Phosphor gave ausn average recovery of 97%.

Interference

The high dilution of the sample with the reagent reduces to a minimum the interference by lipids. Bilirubin below 58 mg/dl does not interfere in the reaction. Haemoglobin interferes at concentrations above 10 g/L.

Precision of the Method

Within-run					
Range	U.M	Mean	S.D.	C.V.(%)	No. run
Low	mg/dl	3.40	0.05	1.54	20
High	mg/dl	7.80	0.07	0.93	20
Between run					
Range	U.M	Mean	S.D.	C.V.(%)	No. run
Low	mg/dl	3.42	0.05	1.28	60
High	mg/dl	7.73	0.06	0.82	60

Sensitivity

At 340 nm, a concentration of about 0.043 mg/dl of Phosphorus can estimate.

References

1. Daly, J.A., Clin. Chem., 18: 263, 1972.
2. Gamst, O. and Try, K., Scand. J. Clin. Lab. Invest. 40 1980.
3. Amador, E. and Urban, J; Clin. Chem. 18, 60, 1977.

Symbols

IVD	In Vitro Diagnostics		Caution
LOT	Batch No.		Product Expiry Date
CONT	Content		Manufactured By
	Read Instructions		Date of Manufacture
	Storage Temperature		Keep Dry
REF	Catalogue No.		Fragile
			Keep away from sun light

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