Phosphorus Kit

CliniQuant - FSR

Ammonium Molybdate Method, End Point

Meril Diagnostics

IVD For *in vitro* diagnostic use
Read this pack insert thoroughly before use

REF	Pack Size	R1 Phosphorus Reagent	R2 Phosphorus Standard
PHOFSR-01	2 x 25ml	2 x 25ml	1 x 5ml

INTENDED USE

This reagent is intended for quantitative determination of Phosphorus concentration in human serum or plasma.

CLINICAL SIGNIFICANCE

In adult human 85% Phosphorus is present in the skeleton and the rest in soft tissues, nucleic acids, phospholipids and in adenosine triphosphate (ATP) as inorganic phosphorus. Increased levels of serum phosphorus are seen in renal diseases, hypoparathyroidism and excessive intake of Vitamin D. Decline levels result in complications such as rhabdomyolysis, osteomalacia and altered red blood cell function.

PRINCIPLE OF THE METHOD

Inorganic phoshorus in strong acidic medium react with ammonium molybdate to form a phosphomolybdate complex. The colourless phosphomolybdate complex is measured directly at 340 nm.

KIT COMPONENTS

Composition

R1 - Phosphorus Reagent : Ammonium Molybdate, Sulfuric acid 213 mmol/l, Surfactant

R2 - Phosphorus Standard : 5.0 mg/dl, Potassium Dihydrogen phosphate 1.3 mmol/l

MATERIALS REQUIRED BUT NOT PROVIDED

Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/ rack, heating bath, controls, saline.

REAGENT PREPARATION, STORAGE & STABILITY

Reagent is ready to use. Keep away from direct light sources.

Stability: up to expiration date on labels at 2-8 °C.

Upon opening of kit, store Reagent R1 at 15 -30 °C and standard at 2-8 °C.

Stability since first opening of vials: preferable within 60 days.

REAGENT DETERIORATION

1. Discard the reagent if absorbance exceeds 0.4 at 340 nm against distilled water.
2. Keep the Standard vial plugged after use, in order to avoid deterioration.

WARNINGS AND PRECAUTIONS

1. Reagent contains strong acid. Do not mouth pipette. It is recommended to handle carefully, avoiding contact with skin and swallow.
2. Specimens should be considered infectious and handled appropriately.
3. Care must be taken to avoid phosphorus contamination. The use of disposable plastic or glass tubes or cuvettes free from phosphorus contamination is strongly recommended. Re-used glassware be soaked in dilute HCl or extran (neutral) and thoroughly rinsed with distilled water and dried.
4. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

Use fresh unhaemolysed serum. Heparinized plasma is acceptable however inorganic phosphate is about 0.2 to 0.3 mg/dl lower than serum. Avoid use of fluoride, citrate, oxalate and EDTA as anticoagulant. Serum is stable for 7 days at 2-8 °C and 6 months at -20 °C.

Programme Parameter for MERILYZER CliniQuant

Reading Mode	End Point
Standard Conc.	5.0 (mg/dl)
Filter – 1 (nm)	340
Temperature	37 °C
Volume (µl)	500
Delay Time (Sec)	5
Reaction Direction	Increase
Reference Low	2.5
Reference High	4.5
Linearity Limit	15

CE
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TEST PROCEDURE

Dispense	Blank	Standard	Sample
Reagent 1	1ml	1ml	1ml
Distilled water	20 µl	-	-
Standard	-	20 µl	-
Sample	-	-	20 µl
Mix, incubate for 5 min at 37°C. Read absorbance of standard (As) and samples (Ax) against reagent blank.			

RESULT CALCULATION

Serum/plasma:

Phosphorus mg/dl = Ax/As x Concentration of Standard

SI conversion factor: 1 mg/dl x 0.323 = 1 mmol/l

EXPECTED VALUES

2.5 – 4.5 mg/dl OR 0.81 – 1.45 mmol/l

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.

Using the recommended Calibrator (BioCal) or the Standard included, calibrate the assay:

a. When using a new reagent or lot

b. When QC values are out of range

PERFORMANCE CHARACTERISTICS

1. Linearity

The linearity is up to 15.0 mg/dl or 4.85 mmol/l.

2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 0.1 mg/dl.

The limit of quantification is 0.2 mg/dl.

3. Interferences

Gross hemolysis, lipaemia and icteric specimens may cause falsely elevated results, a sample blank be set by adding 20 µl sample in 1ml saline.

4. Precision

Intra-assay precision

	Mean	SD	CV
n = 20	mg/dl	mg/dl	%
sample 1	3.82	0.01	0.30
sample 2	6.25	0.03	0.41

Inter-assay precision

	Mean	SD	CV
n = 20	mg/dl	mg/dl	%
sample 1	3.77	0.12	3.27
sample 2	6.30	0.16	2.59

5. Methods Comparison

Comparison was done between reference Phosphorus Reagent and CliniQuant - FSR Phosphorus Reagent (test)

N = 24 $y = 1.063 x + 0.204$

$r^2 = 0.960$

LIMITATIONS

Samples with values above 15 mg/dl should be diluted with 0.9% saline, re-run and results multiplied by dilution factor

2. Discard the reagent if absorbance exceeds 0.3 against distilled water.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

REFERENCES

1. Burtis, C.A., Ashwood, E.R., editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia, W.B. Saunders Company, 1994, p. 1906 – 1910.

2. Data on file: Meril Diagnostics.

IFU/PHOFSR01/00

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Symbols used on Meril Diagnostics labels:

REF	Catalogue No.		Attention See Instruction for Use
LOT	Batch No.	IVD	*In vitro* Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged

EC REP Authorized European Representative in the European Community