INORGANIC PHOSPHORUS SYSTEM PACK

Unicorn 480, Bonavera Chem 480 & Bonavera Chem 400

(Fully Auto Biochemistry Analyzer)

BEACON

Code	Product Name	Pack Size
UNI23	Inorganic Phosphorus System Pack	4 x 40 ml

INTENDED USE

Diagnostic reagent for quantitative *in vitro* determination of Phosphorus in human serum, plasma or urine.

CLINICAL SIGNIFICANCE

More than 80% of the body's phosphate is present in bones as calcium phosphate. The remainder is found intracellularly as organic phosphates such as phospholipids, nucleic acids and ATP or extracellularly as inorganic phosphorus.
There is generally a reciprocal relationship between serum calcium and inorganic phosphorus levels. Increased levels of serum phosphorus is seen in renal diseases, hypoparathyroidism and excessive vitamin D intake.
Decreased levels of phosphorus is seen in rickets, osteomalacia (adult rickets), hyperparathyroidism and in diabetic coma.

PRINCIPLE

Inorganic phosphorus combines with ammonium molybdate in the presence of strong acids to form phosphomolybdate. The formation of reduced phosphomolybdate is measured at 340 nm and is directly proportional to the concentration of inorganic phosphorus present in the sample.

REACTION

Phosphorus + Ammonium Molybdate ⟶ Phosphomolybdate Complex

REAGENT COMPOSITION

R1: Molybdate Reagent

Ammonium Molybdate > 1 mmol/L

REAGENT PREPARATION

Reagents are liquid, ready to use.

STABILITY AND STORAGE

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2–8°C.

On board stability: Min. 30 days if refrigerated (2-10°) and not contaminated.

SPECIMEN COLLECTION AND HANDLING

Use unheamolyse serum or plasma (heparin) or urine.
It is recommended to follow NCCLS procedures (or similar standardized conditions).

Stability in serum / plasma:

7 days at 4–25°C
3 months at -20°C

Stability in urine:

2 days at 20–25°C at pH < 5

Acidify the urine with few drops of conc. Hydrochloric acid.
Dilute 1 + 19 before the assay (result x 20)

CALIBRATION

Calibration with the Beacon Multicalibrator is recommended.

QUALITY CONTROL

It's recommended to run normal and abnormal control sera to validate reagent performance

UNIT CONVERSION

mg/dl x 0.32 = mmol/l

EXPECTED VALUES

Serum

Adult 3 – 4.5 mg/dl
Children 4.0 – 5.5 mg/dl

Unine, 24 h

Adult 0.4 – 1.3 g / 24 h

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

PERFORMANCE DATA

Data contained within this section is representative of performance on Beacon Data obtained in your laboratory may differ from these values.

Limit of quantification: 0.2 mg/dl
Linearity: 15 mg/dl
Measuring range: 0.2 – 15 mg/dl

PRECISION

Intra-assay precision Within run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	5.00	0.04	0.77
Sample 2	7.00	0.04	0.56

Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	9.51	0.187	1.97

COMPARISON

A comparision between Inorganic Phosphorus System Pack (y) and commercially available test (x) using 20 samples gave following results:

y = 0.992x + 0.089 mg/dl
r = 0.998

INTERFERENCES

Following substances do not interfere:
haemoglobin up to 1.25 g/l, bilirubin up to 20 mg/dl, triglycerides up to 500 mg/dl.

WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. To be handles by entitled and professionally educated person.
Reagents of the kit are not classified like dangerous but R2 standard contains less than 0.1% sodium azide - classified as very toxic and dangerous substance for the environment.

WASTE MANAGEMENT

Please refer to local legal requirements.

Parameter for Unicorn 480, Bonavera Chem 480 &

Bonavera chem 400 (Fully Auto Biochemistry Analyzer)

TEST NAME	PHOSPHORUS
FULL NAME	PHOSPHORUS
PRI WAVE	340 nm
SEC WAVE	630 nm
ASSAY/POINT	1 POINT END
START	-
END	33
DECIMAL	2
UNIT	mg/dl
LINEARITY RANGE LOW	0.2
LINEARITY RANGE HIGH	15
SAMPLE VOLUME	2 µ l
REAGENT 1 (R1) VOLUME	200 µl
REAGENT 1 (R2) VOLUME	-
SUBSATRATE DEPLETED	-
LINEARITY	15 mg/dl
OUT OF LINEARITY RANGE	-
CALIBRATION TYPE	2 Point linear
POINTS	2
BLANK TYPE	Reagent
CONCENTRATION BLANK	0.00
CONCENTARTION STD	Refer calibrator value sheet.
SAMPLE VOLUME	2 µ l

NOTE

The program is made as per the in house testing, it can be modified as per requirements.

REFERENCES

1. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. Burtis, C. A., Ashwood, E.R., Bruns, D.E.; 5th edition, WB Saunders Company, 2012.
2. Daly J. A. and Erthingshausen G., Clinical Chem. (1972) 18,263.
3. Wang J. Chem C. C. Osaki, S. Clin. Chem. (1983) 29, 1255.
4. Young D. S. et al Clin. Chem. (1975) 21, 342 D.

SYMBOLS USED ON LABELS

REF Catalogue Number

Manufacturer

See Instruction for Use

LOT Lot Number

CONT Content

Storage Temperature

Expiry Date

IVD In Vitro Diagnostics