BIOLABO
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MANUFACTURER:
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Inorganic PHOSPHORUS U.V. Method

Reagent for quantitative determination of inorganic phosphorus in human plasma and serum or urines.

REF K1015	**R1**	4 x 17 mL
REF K2015	**R1**	4 x 30 mL

TECHNICAL SUPPORT AND ORDERS
Tel: (33) 03 23 25 15 50
support@biolabo.fr
Latest revision: www.biolabo.fr

CE

IVD

Made In France

I: corresponds to significant modifications

INTENDED USE

This reagent is designated for professional use in laboratory (automated method).
It allows the quantification of phosphorus in human serum and plasma, or urines to assess phosphorous homeostasis.

GENERALITIES (1) (2)

An adult human body contains approximately 600 g of phosphates expressed as phosphorus, of which about 85% is bound to calcium in bones and the rest principally in other tissue cells. Most phosphate present in cells is organic and incorporated into phospholipids, nucleic acids, and high energy compounds. Serum/plasma contains approximately 1% of total phosphate as inorganic phosphate, the fraction measured in routine biochemical analysis.
Elevation of phosphorus in serum/plasma is often associated with bone diseases, renal failures, hyperparathyroidism, hypervitaminosis D.
Decreased of phosphorus in serum/plasma are found in case of osteomalacia, vitamin D deficiency, primary hyperparathyroidism.

PRINCIPLE (4) (5)

Method without deproteinization described by Daly and al. modified by Gamst O.K. and Try K.
In an acid medium, phosphate ions form a phosphomolybdic complex with the ammonium molybdate. The absorbance measured at 340 nm is proportional to the concentration of phosphate ions in the specimen.

REAGENTS COMPOSITION

R1 PH Phosphorus Molybdate Reagent

Ammonium Molybdate	0.63	mmol/L
Sulfuric acid	210	mmol/L
Surfactant		

EUH210: Safety Data Sheet (MSDS) available on request

According to 1272/2008/EC regulation, this reagent is not classified as dangerous

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENT PREPARATION

Ready for use.

STABILITY AND STORAGE

Stored away from light, well cap in the original vial at 18-25°C, reagent is stable when stored and used as described in the insert:

Unopened,
- Until the expiry date stated on the label.

Once opened:
- Reagent is stable at least 6 months.
- Discard any reagent if cloudy or if absorbance at 340 nm > 0.800.
- Do not use after expiry date.

SPECIMEN COLLECTION AND HANDLING (2)

Unhemolysed serum or plasma:
Separate from erythrocytes within 1 hour after collection.

- Phosphorus is stable in serum for:
  - ✓several days at 2-8°C.
  - ✓several months at –15°C.

24h Urines:

Collect in acid washed, detergent free container. Acidified urines (pH < 3 with concentrated hydrochloric acid) should be diluted (1+9) in demineralized water free from phosphorus before performing the assay.

- Phosphorus is stable in acidified urines for:
  - ✓6 months.

LIMITS (3)

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

I MATERIALS REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Biochemistry Clinical Analyzer KENZA ONE, KENZA 240TX/ISE or KENZA 450TX/ISE
3. Saline (Reagent Blank)

REFERENCE INTERVALS (2)

In serum or plasma (mg/dL)		(mmol/L)
In cord	3.7-8.1	[1.20-2.62]
Premature	5.4-10.9	[1.74-3.52]
0-10 days	4.5-9.0	[1.45-2.91]
10 days-24 months	4.5-6.7	[1.45-2.16]
24 months-12 years	4.5-5.5	[1.45-1.78]
12-60 years	2.7-4.5	[0.87-1.45]
> 60 years, male	2.3-3.7	[0.74-1.20]
> 60 years, female	2.8-4.1	[0.90-1.32]

In 24 h Urines	(mg/24 h)	(mmol/24 h)
Constant daily diet (*)	< 1000	[< 32.3]
Non-restricted diet	400-1300	[12.9-42.0]

Each laboratory should establish its own normal ranges for the population that it serves.

(*)Constant daily diet: 0.9 at 1.5 g P (29-48 mmol P) and 10 mg Ca/Kg (0.25 mmol Ca/Kg).

I PERFORMANCES

Serum: KENZA 240TX with specimen blank, at 37°C, 340 nm

Linearity Range: between 0.92 (LOQ) and 10 mg/dL

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High level*
Mean (mg/dL)	1.86	3.89	7.15
S.D. mg/dL	0.02	0.06	0.08
C.V. %	0.9%	1.5%	1.2%

Between run N = 12	*Normal level*	*High level*
Mean (mg/dL)	3.88	8.05
S.D. mg/dL	0.05	0.14
C.V. %	1.3%	1.7%

Analytical Sensitivity: approx. 0.1079 abs for 1 mg/dL

Comparison study with commercially available method:

y = 0.990 x + 0.0504 r = 0.9948

Interferences:

Turbidity	No interference up to 0,240OD (7 mmol/L triglycerides)
Ascorbic acid	No interference up to 2500 mg/dL
Total bilirubin	No interference up to 450 µmol/L
Direct bilirubin	No interference up to 90 µmol/L
Haemoglobin	Positive interference from 170 µmol/L
Glucose	No interference up to 1000 mg/dL

Other substances may interfere (see § Limits)

On the board stability: 1 month

Calibration Stability: 1 month

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations

Performances and stability data on KENZA 450TX/ISE and KENZA ONE are available on request.

CALIBRATION (6)

- REF 95015 Multicalibrator *traceable to SRM 3186*

The calibration frequency depends on proper instrument functions and on preservation of the reagent.

QUALITY CONTROL

- REF 95010 EXATROL-N level I
- REF 95011 EXATROL-P level II
- REF 95012 Urinary controls
- External quality control program.

It is recommended to control in the following cases:

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test
2. If control is still out of range, use a new vial of fresh calibrator
3. If control is still out of range, use a new vial of reagent and reassay

If control is still out of range, please contact BIOLABO technical support or your local Agent.

I PROCEDURE

Refer to specific application for specimen used on KENZA Analyzer.

Specimen blanking is recommended.

Values of control sera and Multicalibrator are indicated with or without specimen blank.

Contact support@biolabo.fr for more details used

CALCULATION

The analyzer provides directly final result.
Refer to the instruction of use of KENZA analyzer.

REFERENCES

(1) *TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 1406-1457.*
(2) *Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p.852-855*
(3) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p.3-456 to 3-462*
(4) *DALY J. A. and ERTINGSHAUSEN G.,Clin. Chem., Direct method for inorganic phosphate determination, (1972), 18, p.263-265*
(5) *GAMST O.K., TRY K., Scand. J. Clin. Lab. Invest. (1980), 40, p.483-486*
(6) *SRM: Standard Reference Material ®*

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with