Inorganic Phosphorus (P)

Method: Phosphomolybdate Readduction

Cat .No.	Size	Instrument
GB420E	5×48 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS421E	4×60 ml	For Hitachi917 & OlympusAU640/400/600
GH421E	4×50 ml	For Hitachi902
GX421E	1×100 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-800
GT421E	5×48 ml	For TOSHIBA

INTENDED USE

For the *in vitro* quantitative determination of inorganic phosphorous in human serum.

CLINICAL SIGNIFICANCE[1]

The majority of the body's phosphorous is found in the bone as hydroxyapatite. The remaining phosphate is resent as inorganic phosphate esters. Phosphorous is involved in the intermediary metabolism of carbohydrates and is a component of other physiologically important substances. Thus, increased serum phosphorous may occur in hypervitaminosis, hyperparathyroidism, and renal failure. Reduced serum phosphorous levels are seen in rickets (vitamin D deficiency) hyperparathyroidism, and Fanconis syndrome.

ASSAY PRINCIPLE[2]

Inorganic phosphorous reacts with ammonium molybdate in the presence of an acid to form an ammonium phosphomolybdate complex, which absorbs light at 340 nm. This complex is maintained in solution and its absorbance is enhanced by the addition of surfactant. The increase in color is measured spectrophotometrically and is proportional to the amount of inorganic phosphorous present.

SAMPLE COLLECTION AND PREPARATION[3-6]

1. Use only clear, unhemolyzed serum, separated from the erythrocytes as soon as possible. Erythrocytes contain organic phosphates the can hydrolyze on standing or can be enzymatically cleaved by phosphatases. Inorganic phosphates can then leek through the cell walls, increasing the concentration.
2. Plasma should not be used since anticoagulants may produce falsely low value.
3. Once the serum has been separated, the phosphate content will not change for at least a week when stored in the refrigerator at 2-8℃.

REAGENT COMPOSITION

Contents	Concentration of Solutions
Ammonium Molybdate	0.4 mmol/L
Sulfuric Acid	0.21 mol/L
Surfactant and stabilizer	

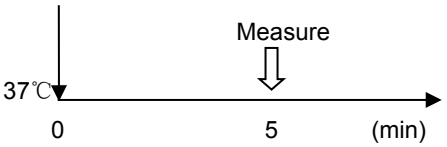
STABILITY AND PREPARATION OF REAGENTS

Reagent comes in a ready to use.
Stable up to the expiry date when stored at 2-8℃.
The Inorganic phosphorous assay kit reagents are stable for 28 days on board.

ASSAY PROCEDURE

Test Procedure for Analyzers (HITACHI 917)
Assay Mode: End Point
Wave Length (main): 340 nm

Sample: 2 µl
R1: 200 µl



1. Mix 2 µl sample with 200 µl R1 and incubate at 37℃ for 5 minutes.
2. Measure the absorbance of the sample (A_{sample}) and calibrator ($A_{calibrator}$) against reagent blank.

CALCULATION

$$\text{Concentration} = \frac{A_{sample} - A_{blank}}{A_{calibrator} - A_{blank}} \times \text{Calibrator value}$$

CALIBRATION

Recommend that this assay should be calibrated using Gcell Calibrator.

QUALITY CONTROL

The integrity of the reaction should be monitored by use of normal and abnormal control sera with known concentrations of inorganic phosphorous. Values should fall within a specific range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

EXPECTED VALUE[7]

Adult serum: 0.87－1.45 mmol/L.
This range should serve only as a guideline. It is recommended that each laboratory establish its own range of expected values since differences exist between instruments, laboratories and local population.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The method is linear up to 5.0 mmol/l. Sample above this concentration should be diluted 1+1 with 0.9% NaCl and reassay. Multiply the result by 2.

PRECISION

The CV of the test should be less than 5%.

Inter assay precision		
N=5	Level1	Level 2
Mean (mmol/L)	1.42	1.99

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CE

Revised 01DEC11 version 0908

SD	0.011	0.014
CV	0.76%	0.72%
Intra assay precision		
N=20	Level1	Level 2
Mean (mmol/L)	1.44	2.12
SD	0.021	0.371
CV	1.45%	1.75%

INTERFERENCE

Bilirubin ≤ 10 mg/dl, Vc ≤ 60 mg/dl, without interference.
TG ≤ 1000 mg/dl, Hemoglobin ≤ 100 mg/dl, interference

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:
Y=1.022X-0.085, R^2=0.998; 175 patient samples were analyzed.

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES

1. Tiez, N.W., Fundamentals of Clinical Chemistry, W. B. Saunders Co., Philadelphia, p. 903(1976)
2. Henry, R.J., Cannon, D.C., and Winkleman, J.W Clinical Chemistry, Principles and Techniques, 2nd. Ed., Harper and Row, Hagerstown, 1974, p.720
3. Tiez, N.W., Textbook of Clinical Chemistry, W.B. Saunders, Philadelphia, 1986, p.1352
4. Goldenberg, H. Ferrnandez, A. Clin. Chem. 12:871(1966)
5. Henry, R. J., et al, Clinical Chemistry: Principles and Techniques, New York, Harper & Row, p.728(1964)
6. Hansk, A., Kao,J., Clin Chem. 14:58(1968)
7. Henry, R. J., et al, Clinical Chemistry: Principles and Techniques 409, New York, Harper & Row, p.728(1974)

INDEX OF SYMBOLS

	Manufacture
	Catalogue Number
	Lot number
	Date of manufacture
	Use by(Expiration date)
	For In-Vitro Diagnostic use only
	Stored at 2-8℃
	Attention:See instruction for use
	Authorized Representative in the European Company

Manufacture：Beijing Strong Biotechnology, Inc.
Address： No. 15, Yanqi North Second Street, Yanqi Economic Development Area, Huairou District, Beijing 101400, P. R. China
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