Cat. No 4-543

DIAGNOSTIC KIT FOR DETERMINATION OF INORGANIC PHOSPHORUS CONCENTRATION

HC – PHOSPHORUS

INTRODUCTION

Phosphorus is present in all body cells as a component of nucleic acids, phospholipids and phosphoproteins. Phosphorus is essential for intracellular storage and conversion of energy (ATP, creatine phosphate) and participates in carbohydrates metabolism. In the blood phosphorus is present as a mixture of inorganic phosphates HPO_4^{-2} and $H_2PO_4^-$. Besides phosphorus and calcium constitute mineral portion of bone. Continuous flux of phosphorus in organism is controlled by parathyroid hormone (PTH), vitamin D and calcitonin. Phosphorus serum level abnormalities are caused usually by disorders of vitamin D metabolism or parathyroid and kidney diseases.

METHOD PRINCIPLE

Direct phosphomolybdate reaction without deproteinization. Phosphate ions form with molybdate ions in acid solution proportional amounts of unreduced phosphomolybdate complex. The concentration of the complex formed is determined by measuring its absorbance at λ=340 nm.

REAGENTS

Package

1-Reagent	6 x 96.5 ml

The reagent is stable up to the kit expiry date printed on the package when stored at 2-8°C. The reagent is stable for 12 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

Concentrations in the test

ammonium molybdate	0.4 mmol/l
sulphuric acid	100 mmol/l
hydrochloric acid	100 mmol/l

Warnings and notes

- Product for in vitro diagnostic use only.
- Contaminated glassware is the greatest source of error. Disposable plastic ware is recommended for the test.
- 1-Reagent is classified as an irritant!

Ingredients: sulphuric acid;
Xi – Irritant.
R 36/38: Irritating to eyes and skin.
S 26-28-30-45: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. After contact with skin, wash immediately with plenty of water. Never add water to this product. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

SPECIMEN

Serum, heparinized plasma (recommended: heparine lithium, sodium or ammonium salt) free from hemolysis, 24-hours urine.
Serum is the preferred specimen. Level of inorganic phosphate in heparinized plasma is about 0.2 to 0.3 mg/dl (0.06 - 0.10 mmol/l) lower than in serum.
Serum should be separated from red blood cells as soon as possible after blood collection, because erythrocytes contain several times higher phosphate concentration than normal serum.
Urine preparation: To prevent phosphate precipitation in urine, specimens should be collected in HCl, 20-30 ml of 6 mol/L for 24-h specimen. Then dilute 1 part of acidified urine with 10 parts of distilled water. Multiply the result by the dilution factor.
Serum and plasma can be stored up to 7 days at 2-8ºC. For longer storage samples should be frozen at -20ºC.
24-hours urine samples can be stored up to 7 days at 2-8ºC. Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

The reagent is ready to use.
This reagent may be used in automatic analyser Hitachi 911/912.
Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:

1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

REFERENCE VALUES [7]

serum / plasma		mg/dl	mmol/l
age:	0 – 10 d	4.5 – 9.0	1.45 – 2.91
	10 d – 24 mo	4.5 – 6.7	1.45 – 2.16
	24 mo – 12 y	4.5 – 5.5	1.45 – 1.78
	12 – 60 y	2.7 – 4.5	0.87 – 1.45
	> 60 y males	2.3 – 3.7	0.74 – 1.20
	> 60 y females	2.8 – 4.1	0.90 – 1.32
24–hours urine		g/24h	mmol/24h
		0.4 – 1.3	12.9 – 42.0

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) for determination in serum or CORMAY URINE CONTROL LEVEL 1 (Cat. No 5-161) and LEVEL 2 (Cat. No 5-162) for determination in urine with each batch of samples.
For the calibration of automatic analysers systems the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) is recommended. **Calibrator and 0.9% NaCl** should be used for calibration.
The calibration curve should be prepared every 12 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analyser Hitachi 912. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 0.22 mg/dl (0.07 mmol/l).

- **Linearity:** up to 14 mg/dl (4.52 mmol/l).
  For higher concentrations dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.

- **Specificity / Interferences**
  Haemoglobin up to 0.16 g/dl, ascorbate up to 62 mg/l, bilirubin up to 20 mg/dl and triglycerides up to 500 mg/dl do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	3.39	0.03	0.82
level 2	7.02	0.03	0.42

Reproducibility (day to day) n = 80	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	3.49	0.05	1.36
level 2	7.15	0.08	1.12

- **Method comparison**

A comparison between phosphorus values determined at Hitachi 912 (y) and at BS-400 (x) using 65 samples gave following results:
y = x - 0.0348 mg/dl;
R = 0.9982 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURA

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