INORGANIC PHOSPHOROUS (PHOS)

UV METHOD
RX DAYTONA PLUS

INTENDED USE

An inorganic phosphorous test system is a device intended for the quantitative *in vitro* determination of inorganic phosphorous concentration in serum and urine. This product is suitable for use on the RX **series** analyser, RX **daytona plus.**

Cat. No.			
PH 8328	R1.	Blank Reagent	4 x 12.7 ml
	R2.	Molybdate	4 x 7.1 ml

GTIN: 05055273209358

FOR PRESCRIPTION USE ONLY

CLINICAL SIGNIFICANCE

The human body contains approximately one kilogram of phosphorous. The calcium phosphate salts which comprise the inorganic substance of bone account for approximately 80% of the total phosphorous content. The remainder is distributed throughout other cells of the body primarily as organic phosphorous in phospholipids and phosphoproteins. In serum most inorganic phosphorus exists in a free form with approximately 15% bound to protein. Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders including parathyroid gland and kidney diseases, and vitamin D imbalance.

ASSAY PRINCIPLE [1]

Inorganic phosphorous reacts with ammonium molybdate in the presence of sulphuric acid to form a phosphomolybdate complex which is measured at 340 nm.

This assay uses an endpoint method and single point calibration.

SAMPLE COLLECTION AND PREPARATION [2]

Serum: Stable for 5 days when stored at +2 to +8°C. Stable for 3 months if stored frozen at - 20°C. Avoid haemolysed samples as haemolysis interferes with the assay. Lipemic samples should not be used with this assay.

Urine: 24 hour urine should be collected in an acid washed, detergent free bottle. Acidify after collection to pH<3.0.

REAGENT COMPOSITION

Contents	Initial Concentration of Solutions
R1. Blank Reagent	
Sulphuric acid	0.36 mol/l
Sodium chloride	154 mmol/l
Detergent	
R2. Molybdate Reagent	
Ammonium molybdate	3.5 mmol/l
Sulphuric acid	0.36 mol/l
Sodium chloride	154 mmol/l

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Solutions R1 and R2 contain sulphuric acid. Avoid ingestion or contact with skin or mucous membranes.

Safety Data Sheets are available on request.

Please dispose of all Biological and Chemical materials according to local guidelines.

The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

STABILITY AND PREPARATION OF REAGENTS

All reagents are ready for use. Stable until expiry date when stored at +15 to +25°C.

MATERIALS PROVIDED

Inorganic Phosphorous Reagent

MATERIALS REQUIRED BUT NOT PROVIDED

Randox Assayed Multisera Level 2 (Cat. No. HN 1530) and Level 3 (Cat. No. HE 1532)
Randox Calibration Serum Level 3 (Cat. No. CAL 2351)
RX **series** Saline (Cat. No. SA 8396)

PROCEDURE NOTES

To avoid the potential for reagent carryover, it is recommended that the testing order of the reagents is confirmed. Please consult the reagent carryover document available on www.randox.com under support and documentation - Reagent product inserts or by contacting Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

The Chemistry Parameters for Randox Dedicated RX **daytona plus** Assays are predefined on the hard drive of the analyser PC. The required programs should be downloaded to the analyser software. Please note that the predefined chemistry parameters use SI units. If alternative units are required, these can be edited by the user. In this case, the technical range should be edited in accordance with the users selected units. All necessary instructions are encoded on the barcode. If the barcode cannot be read by the analyser, enter manually the series of numbers given beneath the barcode. If problems continue, contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

If measurement of urine samples is required, please ensure that the separate urine program on the parameters disk is used.

RX DAYTONA PLUS CALIBRATION

0.9% NaCl solution as zero calibrator and Randox Calibration Serum Level 3 are recommended for calibration.

STANDARDISATION

Randox Calibration Serum Level 3 is traceable to Inorganic Phosphorous reference materials NIST 186Ig.

QUALITY CONTROL

Randox Assayed Multisera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified 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 cleanliness of all equipment in use.
3. Check water, contaminants i.e. bacterial growth may contribute to inaccurate results.
4. Check reaction temperature.
5. Check expiry date of kit and contents.
6. Contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

Quality control requirements should be determined in conformance with government regulations or accreditation requirements.

NORMAL VALUES [2, 3]

Serum: 0.87 - 1.45 mmol/l (2.7 - 4.5 mg/dl)

24 hour urine: 12.9 – 42.0 mmol/d
(0.4 – 1.3 g/d) non restricted diet

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SERUM
SPECIFIC PERFORMANCE CHARACTERISTICS

The following performance characteristics were obtained using the RX **daytona plus**.

INTERFERENCE

The following analytes were tested up to the levels indicated at Inorganic Phosphorous concentrations of 0.710 mmol/l and 2.10 mmol/l and found not to interfere:

	0.710 mmol/l	2.10 mmol/l
Haemoglobin	Interferes	1000 mg/dl
Total Bilirubin	60 mg/dl	60 mg/dl
Conjugate Bilirubin	15 mg/dl	60 mg/dl
Triglycerides	Interferes	Interferes
Intralipid®	1500 mg/dl	1500 mg/dl

500mg/dl concentration of triglycerides interferes with this assay.

Physiological changes in serum or plasma analyte concentrations can be caused by a number of substances. Comprehensive discussion of possible interfering substances, their serum or plasma concentrations, and their possible physiological involvements is beyond the scope of this document. The listed reference contains specific details on known potential interfering substances[4]. The user must remain vigilant to the possible effect on results of unknown interferences from medications or endogenous substances. All patient results must be evaluated in light of the total clinical status of the patient.

REPORTABLE RANGE

Linearity data demonstrates that the reportable range for Phosphorus on the RX **daytona plus** is 0.22 to 11.8 mmol/l**.**

SENSITIVITY

The limit of Quantitation (LoQ), the limit of Detection (LoD) and the limit of Blank (LoB) were determined consistent with CLSI guidelines EP17-A. LoQ is the lowest concentration that can be detected with ≤40% Total error. LoD is the lowest concentration that can be detected to determine the presence or absence of Phosphorus. LoB is the highest concentration that is likely to be observed in a blank sample.

RX daytona plus

Limit of Blank (mmol/l)	0.070
Limit of Detection (mmol/l)	0.091
Limit of Quantitation (mmol/l)	0.22

PRECISION

Precision was evaluated using 3 unaltered human serum samples. All samples were tested in duplicate twice per day for 20 days.

WITHIN RUN PRECISION

	Level 1	Level 2	Level 3
Mean (mmol/l)	0.706	1.46	2.28
SD	0.019	0.031	0.042
CV (%)	2.67	2.10	1.83
n	80	80	80

TOTAL PRECISION

	Level 1	Level 2	Level 3
Mean (mmol/l)	0.706	1.46	2.28
SD	0.032	0.061	0.084
CV (%)	4.61	4.17	3.69
n	80	80	80

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

Y = 1.0241X – 0.0412
and a correlation coefficient of r = 0.9995

60 patient samples were analysed spanning the range 0.31 to 5.71 mmol/l.

URINE
SPECIFIC PERFORMANCE CHARACTERISTICS

The following performance characteristics were obtained using the RX **daytona plus**.

REPORTABLE RANGE

Linearity data demonstrates that the reportable range for phosphorous on the RX **daytona plus** is 0.90 – 129 mmol/L.

LINEARITY

The method is linear to 129 mmol/l (399 mg/dl).

SENSITIVITY
The minimum detectable concentration of inorganic phosphorous with an acceptable level of precision was determined as 0.90 mmol/l (2.79 mg/dl).

PRECISION
Precision was evaluated using 2 unaltered human urine samples. All samples were tested in singlicate twice per day for 22 days.

WITHIN RUN PRECISION

	Level 1	Level 2
Mean (mmol/l)	11.44	29.64
SD	0.20	0.48
CV (%)	1.7	1.6
n	44	44

TOTAL PRECISION

	Level 1	Level 2
Mean (mmol/l)	11.44	29.64
SD	0.35	0.98
CV (%)	3.1	3.3
n	44	44

CORRELATION
This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

Y = 0.97X – 0.18
and a correlation coefficient of r = 0.995

65 patient samples were analysed spanning the range 1.66 to 121 mmol/l.

REFERENCES

1. Henry, R.J., Clinical Chemistry, Principles and Techniques, 2nd Edition, Harper and Row, p. 525, 1974.
2. Tietz, N., Clinical Guide to Laboratory Tests, W.B. Saunders Company, Philadelphia 1983; **5**:384.
3. Tietz, N.W. *Clinical Guide to laboratory tests.* 2nd edition. Philadelphia, Pa: WB Saunders Co.; 1990: 444-446.
4. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Washington, DC: AACC Press; 2000.

The presence of a vertical bar in the margin indicates a technical update from the previous revision.

EC REP

Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

Revised 09 Jan 24 ld

THIS PAGE IS INTENTIONALLY BLANK