DIAGNOSTICA PRODUCTS

Liquid Reagents – ready to use

PHOSPHORUS INORGANIC
Molybdate

Single Reagent

Diagnostic reagent for quantitative in vitro determination of phosphorus in human serum, plasma or urine on photometric systems.

Ref.No.	Kit Size	Content
DIA010182	5 x 25 ml	Single Reagent
DIA010183	5 x 50 ml	Single Reagent
DIA010184	5 x 100 ml	Single Reagent

Additionally offered:

DIA060090	1 x 3 mL	**Phosphorus STANDARD**
DIA040012	1 x 3 mL	**Diacal Auto** (Calibrator)
DIA030012	1 x 5 mL	**Diacon N** (Control Normal)
DIA030022	1 x 5 mL	**Diacon P**(Control Abnormal)
DIA030030	1 x 5 mL	**Diacon Urine Level 1** (Control Normal)
DIA030035	1 x 5 mL	**Diacon Urine Level 2** (Control Abnormal)

TEST PARAMETERS

Method: UV, Endpoint, Increasing reaction, Phosphomolybdate

Wavelength: 340 nm, Hg 334nm, Hg365nm

Temperature: 20 – 25°C, 37°C

Sample: Serum, heparin plasma, urine

Linearity: up to 15 mg/dL(4.84 mmol/L)

Sensitivity: The lower limit of detection is 0.7 mg/dL(0.23 mmol/L).

SUMMARY [1,2]

Phosphorus exists in the body almost exclusively as phosphate, mainly as inorganic substance of the bones, but also in cells in phospholipids and nucleic acids as well as in adenosine triphosphate, which is involved in the energy transfer. In plasma it is present as calcium phosphate; therefore, in level of plasma phosphorus is strongly associated with that of calcium levels. Measurement of phosphorus in serum and urine is mainly performed to detect disorders of kidneys, bones and parathyroid glands. Increased concentrations are found in renal failure, hypoparathyroidism, pseudo-hyperparathyroidism and vitamin D deficiency. Additional information can be obtained by supplementary measurement of calcium.

TEST PRINCIPLE

In sulfuric acid solution phosphate reacts with ammonium molybdate to form a yellow phosphorus molybdate complex
Maximum complex absorption is at 340 nm. It is proportional to the concentration of inorganic phosphate in the sample.

REAGENT COMPOSITION

COMPONENTS:	CONCENTRATION	
Ammonium Molybdate	0.4	mmol/L
Sulphuric acid	210	mmol/L

REAGENT PREPARATION

The reagent is ready to use.

REAGENT STABILITY AND STORAGE

Conditions: Protect from light.
Close immediately after use.
Do not freeze the reagent.
Avoid contamination.

Storage: at 2 – 25°C

Stability: up to the expiration date

SAMPLE PREPARATION

Urine: For collection of 24 h urine add 10 ml of 10 g/dLHClinto the collection bottle to avoid phosphate precipitations.
Dilute urine 1+10 with dist water before determination and multiply the result by 11.

SAMPLE STABILITY AND STORAGE [4]

Stability:

in serum / plasma:	at 20 – 25 °C	1 day
	at 4 – 8 °C	4 days
	at -20 °C	1 year
in urine (pH <5):	at 20 – 25 °C	2 days

Discard contaminated specimens. Freeze only once!

MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution (9 g/L)
General laboratory equipment

STANDARD

(not included in the kit – has to be ordered separately)
Concentration: 5 mg/dL (1.61 mmol/L)
Storage: 2 – 25°C
Stability: up to the expiration date
Close immediately after use! Avoid contamination!

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Pipette into test tubes	Blank	Std./Cal	Sample
Reagent	1000 µL	1000 µl	1000 µL
distilled water	10 mL	-	-
Standard/Calibrator	-	10 µL	-
Sample	-	-	10 µL
Mix incubate for 5 min. at 20 – 25°C/37°C . Measure absorbance of std./cal. and sample against reagent blank within 60 minutes.			

CALCULATION

Serum/Plasma:

$$\text{Phosph. [mg/dL]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std/Cal}} \times \text{Conc. Std/Cal [mg/dl]}$$

Urine:

$$\text{Phosph. [mg/dL]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std/Cal}} \times \text{Conc. Std/Cal [mg/dL]} \times 11$$

UNIT CONVERSION

Phosphorus [mg/dL] x 0.3229 = Phosphorus [mmol/L]
Phosphorus [mmol/L] = Phosphate [mmol/L]
Phosphorus [mg/dL] x 3.06619 = Phosphate [mg/dL]

REFERENCE RANGE *

Serum/Plasma [1]:		
Children	mg/dL	mmol/L
1 – 30 days	3.9 - 7.7	1.25 – 2.50
1 – 12 months	3.5 – 6.6	1.15 – 2.15
1 – 3 years	3.1 – 6.0	1.00 – 1.95
4 – 6 years	3.3 – 5.6	1.05 – 1.80
7 – 9 years	3.0 – 5.4	0.95 – 1.75
10 – 12 years	3.2 – 5.7	1.05 – 1.85
13 – 15 years	2.9 – 5.1	0.95 – 1.65
16 – 18 years	2.7 – 4.9	0.85 – 1.60
Adults	2.6 – 4.5	0.84 – 1.45
Urine[3]:	0.4 – 1.3 g/24h	12.9 – 42.0 mmol/24h

* Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

LINEARITY, MEASURING RANGE

The test has been developed to determine phosphorus concentrations within a measuring range from 0.7 – 15 mg/dL (0.23 – 4.84 mmol/L).

DIAGNOSTICA PRODUCTS, RTE DE GABES KM 9 Z.I THYNA AL JADIDA SFAX, TUNISIA.
Tel. +216 74 68 79 40 Fax. +216 74 68 79 32

REV. 01, 25.10.2017

When values exceed this range, samples should be diluted 1 + 1 with NaCl (9 g/L sodium chloride in water) and the results multiplied by 2.

SENSITIVITY/LIMIT OF DETECTION

The lower limit of detection is 0.7 mg/dL(0.23 mmol/L)

PRECISION (at 37°C)

Intra-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	4.42	0.08	1.87
Sample 2	8.43	0.07	0.85
Sample 3	10.8	0.13	1.20

Inter-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	4.34	0.13	2.99
Sample 2	8.20	0.27	3.32
Sample 3	10.6	0.31	2.95

SPECIFICITY/INTERFERENCES

no interference up to:

ascorbic acid	30 mg/dL
bilirubin	20 mg/dL
hemoglobin	150 mg/dL
triglycerides	800 mg/dL

METHOD COMPARISON

A comparison between Diagnostica Phosphorus (y) and a commercially available test (x) using 107 samples gave following results: y = 1.041x – 0.20 mg/dl; r = 0.99.

CALIBRATION

The assay requires the use of a Phosphorus Standard or a Calibrator.
We recommend the Diagnostica **Phosphorus Standard** and the Diagnostica multi calibration serum **Diacal Auto**.
The assigned values of the calibrator have been made traceable to a primary phosphorus standard (traceable to the reference material NIST-SRM 723).

QUALITY CONTROL

All control sera with Phosphorus values determined by this method can be used.
We recommend the Diagnostica serum controls **Diacon N** (control serum with values in the normal range) and **Diacon P** (control serum with values in the abnormal range) as well as the Diagnostica urine controls **Diacon Urine Level 1** (control urine normal) and **Level 2** (control urine abnormal).
Each laboratory should establish corrective action in case of deviations in control recovery.

AUTOMATION

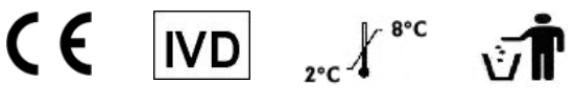
Special applications for automated analyzers can be made on request.

WARNINGS AND PRECAUTIONS

1. Reagent: Warning
   H290: May be corrosive to metals.
   P234: Keep only in original container.
   P280: Wear protective gloves/protective clothing/eye protection.
   P390: Absorb spillage to prevent material damage.
2. In very rare cases, samples of patients with gammopathy might give falsified results [6].
3. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
4. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
5. For professional use only!

WASTE MANAGEMENT

Please refer to local legal requirements.



DIAGNOSTICA PRODUCTS, **RTE DE GABES KM 9 Z.I THYNA AL JADIDA SFAX, TUNISIA.**
Tel. +216 74 68 79 40 Fax. +216 74 68 79 32

REV. 01, 25.10.2017