# PHOSPHORUS-INORGANIC

**Molybdate**

**Diagnostic reagent for determination of Phosphorus concentration.**

Liquid. Mono Reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

| Ref No | Pack | Ref No | Pack | Ref No | Pack | Ref No | Pack |
|---|---|---|---|---|---|---|---|
| A2290 | 5 x 100 mL | R2290 | 1364 Tests | BY2290 | 4545 Tests | K2290 | 2273 Tests |
| A2291 | 5 x 50 mL | R2291 | 455 Tests | BY2291 | 3182 Tests | K2291 | 1091 Tests |
| T2291 | 1471 Tests | S2290 | 1636 Tests | N2290 | 758 Tests | M2290 | 2273 Tests |
| L2290 | 5000 Tests | S2291 | 1636 Tests | N2291 | 424 Tests | M2291 | 1364 Tests |
| L2291 | 2667 Tests | DM2290 | 990 Tests | | | | |

## INTENDED USE

The test is applied for the quantitative determination of phosphorus in serum or heparinised plasma.

## TEST PRINCIPLE

The phosphate ions react with ammonium molybdate to form a phosphomolybdate complex. The colourless phosphomolybdate complex can be measured directly by ultraviolet (UV) absorption at 340 nm. An acid pH is necessary for the formation of complexes.

## TEST PARAMETERS

| | |
|---|---|
| Method | : Colorimetric, Endpoint, Increasing reaction |
| Wavelength | : 340 nm |
| Temperature | : Room temperature, 37°C |
| Sample | : Serum or heparinized plasma |
| Linearity | : 0.8 mg/dL - 20 mg/dL |

## REAGENT COMPOSITION

| | |
|---|---|
| Ammonium molibdate | ≤ 0.6 mmol/L, |
| Sulphuric acid | ≤ 0.25 mol/L, |
| Surfactant. | |

## REAGENT PREPARATION

Use reagent is ready to use.
Stability of reagents is up to expiration date on labels at 2-8°C.
Stability of first opening of vials is longer than 60 days at 2-8°C.

## REAGENT STABILITY AND STORAGE

Once opened vials (reagent 1) are stable minimum 30 days at 2-8°C at optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

## SAMPLE

Serum is the preferred specimen. Although heparinized plasma is acceptable, levels of inorganic phosphate are about 0.2 to 0.3 mg/dL lower than in serum. Anticoagulants such as citrate, oxalate, and EDTA interfere with formation of the phosphomolybdate complex and should not be used. Inorganic phosphate in whole blood specimens may either decrease or increase with time, depending on the type of specimen, temperature, and duration of storage. Levels in plasma or serum are increased by prolonged storage with cells at room temperature or 37 °C; it is important to promptly separate serum or plasma from erythrocytes. Hemolyzed specimens are unacceptable because erythrocytes contain high concentrations of organic phosphate esters, which can be hydrolyzed to inorganic phosphate during storage. Inorganic phosphate increases by 4 to 5 mg/dl per day in hemolyzed specimens stored at 4°C. Glucose phosphate, creatine phosphate, and other organic phosphates may also be hydrolyzed by assay conditions, resulting in overestimation of inorganic phosphate levels.

Phosphate is considered to be stable in serum that has been separated from the clot for days at 4°C and months when frozen. Urine samples should be collected in 6 mol/L HCl, 20-30 ml for a 24 hours specimen, to avoid precipitation of phosphate complexes. Dilute urine samples 1:20 with purified water before assay.

## TEST PROCEDURE

**Sample Start**

There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

## CALCULATION

$$\frac{\text{A Sample}}{\text{A Standard}} \text{ x conc. of standard}$$

= mg Phosphorus / dL serum or plasma

**Unit Conversion**

mg/dL x 0.3229 = mmol/L

## REFERENCE INTERVAL (NORMAL VALUES) (Based on CLSI C28-P Document)*

| | |
|---|---|
| Serum/plasma (adults) | : 2.5 - 4.5 mg/dL (0.81 - 1.45 mmol/L) |
| Serum/plasma (children) | : 4.0 - 7.0 mg/dL (1.29 - 2.26 mmol/L) |
| Urine (nonrestricted diet) | : 0.4 - 1.3 g/24h (12.9 - 42.2 mmol/24h) |

*It is recommended that each laboratory establish its own reference range.

## QUALITY CONTROL AND CALIBRATION

The assay requires any commercially available, suitable standard or Calibrator. We recommend:

ARCAL Calibrator ("Arcal Auto")
**Cat. No.** A39050

Commercially available control material with established values determined by this method may be used. We recommend:

"ARCON N", Assayed Control Serum Normal
**Cat.No. A3910**

"ARCON P", Assayed Control Serum Abnormal
**Cat.No. A3920**

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 15 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

## PERFORMANCE CHARACTERISTICS

**Low linearity:** 0.8 mg/dL.

**High Linearity:** The method is linear up to 20 mg/dL.
If the limit value is exceeded, it is suggested to dilute sample 1+9 with distilled water and to repeat the test, multiplying the result by 10.

Linearity may considerably vary depending on the instrument used.

**Precision Studies (Based on CLSI EP5 Doc.):**

**Repeatibility (within run) (Intra-assay)**

| Mean conc. | SD | CV | n |
|---|---|---|---|
| 3.50 | 0.05 | 1.50% | 10 |
| 5.87 | 0.11 | 1.90% | 10 |

**Reproducibility (run to run) (Inter-assay)**

| Mean conc. | SD | CV | n |
|---|---|---|---|
| 3.41 | 0.08 | 2.40% | 20 |
| 5.84 | 0.11 | 1.90% | 20 |

**Sensitivity (LOD) (Based on CLSI EP17 document):** The limit of detection is 0.4 mg/dL.

**Trueness:** Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

**Interferences:** No interference was observed by the presence of:

Bilirubin ≤ 25 mg/dl
Hemoglobin ≤ 100 mg/dl
Hemolysis interferes.

Both positive and negative interferences with lipemic samples have been observed.

**Methods comparison:** A comparison between Archem and a commercially available product gave the following results:

Phosphorus Archem = x
Phosphorus competitor = y
N = 102
Y = 1.005x - 0.109 mg/dl $r^2$ = 0.975

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

## NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.

4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1 & R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

## PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

## ABBREVIATIONS

CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

## REFERENCES


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## SYMBOLS

| | |
|---|---|
| IVD | Only for invitro diagnostic use |
| LOT | Lot of manufacturing |
| R1 | Reagent 1 |
| CONC | Concentration |
| INGRED | Reagent Ingredients |
| REF | Reference Number (Catalog No) |
| SN | Serial Number |
|  | Expiration date |
|  | Storage temperature interval |
|  | Read the directions |
|  | Biological risk |

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