PHOSPHORUS

Diagnostic reagent for determination of Phosphorus concentration.
Liquid. Monoreagent. Store at +2/+8°C. For in Vitro Diagnostic Use (IVD). Do not freeze.

Ref No	Pack
MH-242	120 mL
MH-243	40 mL

Changes made in the instructions for use are marked as grey.

INTENDED USE

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

TEST SUMMARY AND PROCEDURE [1, 2, 3, 4, 5]

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
Linearity : 20 mg/dL

REAGENT COMPONENTS

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

REAGENT PREPARATION

Reagents are ready for use.

REAGENT STABILITY AND STORAGE [6]

Reagents are stable at +2/+8˚C till the expiration date stated on the label which is only for closed vials.

Once opened vials are stable for 45 days at +2/+8°C in optimum conditions. On board stability is strongly related to auto analyzers' cooling specification and carry-over values.

Reagent stability and storage data have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol.

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 erythyrocytes. 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.

Unit Conversion:
mg/dL x 0.3229 = mmol/L

REFERENCE INTERVAL (NORMAL VALUES) [7]

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 normal range.

Reference interval has been verified by using CLSI EP28-A3c protocol.

QUALITY CONTROL AND CALIBRATION

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

ARCON N (Level I Control) Lyophilized
Ref.No: VT-001

ARCON P (Level II Control) Lyophilized
Ref.No: VT-002
The assay requires the use of an Arcal Auto Calibrator. We recommend:

ARCAL AUTO
Ref.No: VT-003

Calibration Stability: It strongly depends on the application characteristics of in-use auto analyser and capacity of cooling. Calibration stability is 20 days.

If controls are not within acceptable limits, calibration is required and each laboratory should establish its own Quality Control diagrams and corrective and preventive action procedures.

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

PERFORMANCE CHARACTERISTICS

Limit of Detection (LoD): The limit of the test detection is 0.4 mg/dL.

Limit of Quantitation (LoQ) [LoQ values are based on Coefficient of Variation Percentage (CV) ≤ 20%]**:**[8] 0.8 mg/dL.

LoD and LoQ values have been verified by using CLSI EP17-A protocol.

High Linearity: The method is linear up to 20 mg/dL.
For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilution factor.

Linearity may considerably vary depending on the instrument used.

Precision Studies:[9]
Repeatibility (Within Run)

Mean Concentration	SD*	CV%	n
3.80 mg/dL	0.04	1.23	40
7.33 mg/dL	0.06	0.86	40

Repeatibility (Day-to-Day Run)

Mean Concentration	SD	CV%	n
3.48 mg/dL	0.08	2.30	84
7.57 mg/dL	0.19	2.48	84

*SD: Standard Deviation

*CV: Variation Coefficient

±10% CV% deviations between devices can be observed

Precision Studies data have been verified by using CLSI EP05-A3 protocol.

Method Comparison:[10, 11]
Correlation with a comparative method is: r= 0.975
According to Passing-Bablok Fit:
Slope: 1.005
Intercept: -0.109

Interference:[3, 4, 12]
No significant interactions were observed for lipemia up to the interferent concentration given.

Interferant and Concentration	Phosphorus Target (mg/dL)	N	%Observed Recovery
Lipemi 2149,2 mg/dL	3,33	3	103

Non-hemolysis and non-icteric samples should be used.

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

The acceptable interference limit is set 10% below the highest interference concentration within ± 10% recovery of the target.

Interferences may affect the results due to medication or endogenous substances.

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

WARNINGS AND PRECAUTIONS

IVD**:** For in Vitro Diagnostic use only.
Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines.
Contains sodium azide.
CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

Danger

EUH032	:Releases a very toxic gas if contacts with acid.
H317	:May cause allergic skin reaction.

Precaution

P280	:Use protective gloves / clothes / glasses / mask.
P264	:Wash your hands properly after using.
P272	:Contaminated work clothes should not be allowed to be used outside of the workplace.

Intervention

P302+P352	:Wash with plenty of water and soap if it contacts with skin.
P333+P313	:Seek medical help if it irritates your skin or develops rash.
P362+P364	:Remove contaminated clothes and wash properly before using.

Disposal

P501	:Dispose the vials and contents according to the local regulations.

REFERENCES

1. Tietz, N.W., Fundamentals of Clinical Chemistry, p. 940, W.B. Saunders Co., Philadelphia, 1987.
2. Tietz NW. Clinical Guide to Laboratory Test. 2nd ed. Philadelphia, PA: WB Saunders Company; 1995,52.
3. Tietz NW. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia, PA: WB Saunders Company; 1995:88-91.
4. Tietz NW, ed. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia: WB Saunders 1995:919.
5. Tietz Fundamentals of Clinical Chemistry. 5th ed. Burtis CA, Ashwood ER, eds. Philadelphia, PA: WB Saunders Company; 2001:605.
6. Clinical and Laboratory Standards Institute (CLSI). Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline. CLSI Document EP25-A. Wayne, PA: CLSI; 2009.
7. Clinical and Laboratory Standards Institute (CLSI). Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition. CLSI Document EP28-A3c. Wayne, PA: CLSI; 2010.
8. Clinical and Laboratory Standards Institute (CLSI). Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline.CLSI Document EP17-A. Wayne, PA: CLSI; Vol. 24 No. 34.
9. Clinical and Laboratory Standards Institute (CLSI). Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014
10. Passing-Bablok W et al. A General Regression Procedure for Method Transformation. J Clin Chem Clin Biochem 1988;26.783-79.
11. Clinical and Laboratory Standards Institute (CLSI). Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition; Approved Guideline.CLSI Document EP09-A2. Wayne, PA: CLSI; Vol. 22 No. 19.
12. Clinical and Laboratory Standards Institute (CLSI). Interference Testing in Clinical Chemistry; Approved Guideline.CLSI Document EP07. Wayne, PA: CLSI; 3rd Edition.CHERIAN G., SOLDIN ST. Clin. Chem. 27/5:748-752 (1981)
13. Wu, Alan H.B. Tietz Clinical Guide to Laboratory Tests. 4th ed. Saunders Elsevier, St. Louis, MO: 2006, 992-996.
14. Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).
15. Young DS. Effects of Drugs on Clinical Laboratory Tests. 3rd ed. Washington: AACC Press; 1990.
16. Eisenman G. Glass Electrodes for Hydrogen and Other Cations, Principles and Practice. New York: Marcel Dekker Inc.; 1967:2.
17. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 241-7.
18. Yee H.Y. - Clin. Chem. 14, 898 (1968).
19. STEIGE H., JONES J.D., Clin. Chim. Acta 103:123 (1980)
20. LEO G. MORIN, JEROME PROX, Clin. Chim. Acta 46:43 (1973)
21. Clinical and Laboratory Standards Institute (formerly NCCLS). Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Second Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2004. NCCLS Document EP05-A2.

Archem Sağlık Sanayi ve Tic. A.Ş. (With official contract based manufacturing agreement with Validity Sağlık Hiz.Sanayi A.Ş. Company)
Mahmutbey Mah. Halkalı Cad. No:124 Kat:4
Bağcılar/İstanbul/Türkiye
Tel: + 90 212 444 08 92
Fax: +90 212 629 98 89
info@archem.com.tr www.archem.com.tr
info@validity.com.tr www.validity.com.tr

CE

SYMBOLS

IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
R1	Reagent 1
GTIN	Global Trade Item Number
REF	Reference Number
GLP	Good Laboratory Practices
FOR USE WITH	Identifies Products to Be Used Together
PRODUCT OF TURKEY	Product of Turkey
	Manufacturer
	Expiration Date
	Temperature Limits
	Consult Instructions for Use
	Caution
	Number of Tests