TECO DIAGNOSTICS
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PHOSPHORUS
U.V. METHOD
TC MATRIX 240/480

INTENDED USE
For the quantitative determination of inorganic phosphorus in serum or plasma on TC Matrix analyzers.

SUMMARY AND EXPLANATION OF THE TEST
The majority of the body's phosphorus is found in the bone as hydroxyapatite. The remaining phosphate is present as inorganic phosphate and phosphate esters. Phosphorus is involved in the intermediary metabolism of carbohydrates and is a component of other physiologically important substances. Thus, increased serum phosphorus may occur in hypervitaminosis, hypoparathyroidism, and renal failure. Reduced serum phosphorus levels are seen in rickets (vitamin D deficiency) hyperparathyroidism, and Fanconi's syndrome. The determination of inorganic phosphorus has been based on the reaction of molybdate with phosphate to produce the phosphomolybdenum blue complex, which is measured photometrically. However, many of the components in these reagents are unstable and had to be stored separately. Unreduced phosphomolybdate complex is measured directly in UV range 340 nm in the present method.
The TC Matrix System automatically proportions the appropriate sample and reagent volumes into the cuvette. The system monitors the change in absorbance at 340 nanometers. This change in absorbance is directly proportional to the concentration of phosphorus in the sample and is used by the TC Matrix System to calculate and express the phosphorus concentration.

$$\text{Phosphorus} + \text{Ammonium Molybdate} \xrightarrow{H_2SO_4} \text{Phosphomolydate Complex.}$$

REAGENT CONTENTS:
Each kit contains: Twelve Phosphorus Reagent (12×20 ml)
Instruction Insert.

REAGENT PREPARATION
No preparation is required.

REAGENT COMPOSITION
Ammonium Molybdate: 2.5 mmol/L
pH: <1.0
Also non-reactive chemicals for optimal system performance.

REAGENT STORAGE AND STABILITY
Phosphorus Reagent stored unopened at 2ºC to 8ºC stable until the expiration date on the bottle label. Once opened, Phosphorus Reagent is stable for 30 days.
DO NOT FREEZE.

SPECIMEN COLLECTION AND HANDLING
1. The test can be performed on serum, plasma. For serum, blood is drawn into a tube which does not contain anticoagulant and it is allowed to clot. The serum should then be separated from the clot within two hours from the time of collection.
2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum and plasma should be stored at 2ºC to 8ºC. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15ºC to -20ºC. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.
3. For plasma, add whole blood directly into a tube containing anticoagulant. Acceptable anticoagulants are listed in the "LIMITATIONS" section.

CALIBRATION
1. Calibrator required: TECO MULTI Calibrator (not included in kit)
2. The system must have a valid calibration in memory before controls or patient samples can be run.
3. The TC Matrix system will automatically perform checks on the calibration and produce data at the end of calibration.

Note: Refer to the TC Matrix manual for further instructions on calibrating the instrument

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT
TECO MULTI Calibrator
At least two levels of control material.

LIMITATIONS
1. The anticoagulants EDTA, Potassium Oxalate, Sodium Fluoride and Sodium Citrate were found to be incompatible with this method.
2. The anticoagulants Ammonium Heparin, Lithium Heparin and Sodium Heparin were found to be compatible with this method.

INTERFERENCE
1. Hemoglobin levels up to 400 mg/dl, Triglyceride levels up to 1000mg/dl and Bilirubin levels up to 30 mg/dl were found to exhibit negligible interference.
2. On this method, refer to the work of Young for a review of drug and comprehensive list of substances effect on Phosphorus level.

EXPECTED VALUE
2.5 to 4.6 mg/dL or 0.83 to 1.48 mmol/L

PRECAUTIONS:
1. For in vitro diagnostic use only.
2. Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.
3. Each laboratory should perform the quality control testing to ensure the results are reliable before running the specimens.

PROCEDURES

Test Name:	PHOS	R1:	300
Full Name:	Phosphorus	R2:	0
Pri. Wave:	340 nm	SAMPLE VOLUME:	6.0
Sec. Wave:	405 nm	Calibration Type:	2 point linear
Assay/ Point:	1 point end	K Value:	11.7801
Start - End:	1 - 9	Point:	2
Decimal place:	2	Blank Type:	Reagent
Unit:	mg/dL	Point 0 (Blank) Con.:	0.0
Linearity Range:	1.0000 - 12.000	Point 1 (STD) Con.:	Calibrator/ standard
Correlation Factor:	1.0000 - 0.0000		

PERFORMANCE CHARACTERISTICS

Analytical Range: 1.0- 12.0 mg/dL
For phosphorus analyte by Phosphorus Reagent on TC Matrix System, this method has been demonstrated to be linear from 1.0-12.0 mg/dL

Accuracy: Comparison study was performed on TC Matrix System from 40 samples. Beckman Coulter Phosphorus Reagent was used to compare with Phosphorus Reagent. The results of this study in yield a correlation coefficient of 0.99 with a regression equation of y=0.99x +0.6.

Precision: Within Run precision for Phosphorus Reagent Set was determined following a modification of NCCLS EP5-A. Two commercial human serum were assayed on TC Matrix System for 25 times.

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	4.3	7.5
Standard Deviation (mg/dl)	0.11	0.15
Coefficient of Variation (%)	2.4	2.7

Run-Day precision for Phosphorus Reagent was determined following a modification of NCCLS EP5-A. Two commercial human serum were assayed on TC Matrix Systems five times per day for five days for the total of 25 values.

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	4.3	7.5
Standard Deviation (mg/dl)	0.12	0.14
Coefficient of Variation (%)	3.0	2.8

REFERENCES:

1. Goldenberg H, Femandez A, Clin. Chem., 12:871,1966.
2. Young DS, Thomas DW, Friedman RD, Pestaner LG, Clin. Chem., 18: No. 10,1972.
3. Tietz, N.W.," Specimen Collection and Processing; Sources of Biological Variation," Textbook of Clinical Chemistry, 2nd Edition, W.B. Saunders, Philadelphia, PA (1994)
4. National Committee for Clinical Laboratory Standards. Approved Guideline, NCCLS publication C28-A, Villanova, PA (1994).
5. Henry, J. B., ed., Clinical Diagnostics and Management by Laboratory Methods, 18th Edition, W.B. Saunders, Philadelphia.
6. Tietz,N.W., ed., Clinical Guide to Laboratory Tests, 2 nd Edition, W.B. Saunders, Philadelphia, PA (1990)
7. National Committee for Clinical Laboratory Standards, Method Comparison and Bias Estimation Using Patient Samples; Tentative Guideline, NCCLS Publication EP9-T, Villanova, PA (1993)
8. National Committee for Clinical Laboratory Standards, Precision Performance of Clinical Chemistry Devices; Tentative Guideline, 2nd Edition, NCCLS publication EP5-T2, Villanova, PA (1992)
9. National Committee for Clinical Laboratory Standards, National Evaluation Protocols for Interference Testing, Evaluation Protocol Number 7, Vol. 4, No, June 1984.
10. Young, D.S., Effects of Drugs on Clinical Laboratory Tests, 3rd. Ed., AACC Press, Washington DC, 1990, 3:104-106.

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Manufactured by:

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