TECO DIAGNOSTICS
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ALKALINE PHOSPHATASE (ALP) KINETIC METHOD
TC MATRIX-160/240

INTENDED USE
For the quantitative determination of alkaline phosphatase activity in serum or plasma on TC Matrix analyzers.

SUMMARY AND EXPLANATION OF THE TEST
Alkaline phosphatase (ALP) present in serum is derived primarily from the liver and intestine with little amount from bone. Increase of ALP activities are, therefore, indicators of hepatobiliary or bone disorder. In hepatobiliary disease, biliary cirrhosis produces exceptionally high levels of serum ALP. Infiltrative disease and cholangiolitic hepatitis are accompanied by significant elevations of ALP. Highly elevated ALP level may also occur in infectious mononucleosis.

Among the bone diseases, the highest levels of serum ALP activity are encountered in Paget's disease and bone cancer. Moderate rises are observed in osteomalacia, rickets, faconi syndrome, primary hyperparathyroidism and secondary hyperparathyroidism. An increase of alkaline phosphatase of up to 2 to 3 times normal is observed in women in the third trimester of pregnancy.

Moderate elevations of ALP may be seen in several disorders that do not involve the liver or bone. Among these are Hodgkin's disease, congestive heart failure, ulcerative colitis, regional enteritis, and intraabdominal bacterial infections.

$$\text{p-nitrophenylphosphate} + H_2O \xrightarrow[Mg^{++}]{ALP} \text{p-nitrophenol (yellow)} + \text{phosphate}$$

REAGENT PREPARATION
No preparation is required.

REAGENT COMPOSITION
p-Nitrophenylphosphate: 15 mmol/L
2-Amino-2-methyl-1-propanol: 350 mmol/L
Also non-reactive chemicals for optimal system performance.

REAGENT STORAGE AND STABILITY
Teco Alkaline Phosphatase reagents stored unopened at 2ºC to 8ºC are stable until the expiration date shown on the bottle label. Once opened, Teco Alkaline Phosphatase Reagent is stable for 7 days, or until expiration date on the label, whichever occurs first.
DO NOT FREEZE.

SPECIMEN COLLECTION AND HANDLING
1. The test can be performed on serum or plasma. For serum, blood is drawn into a tube which does not contain anticoagulant and is allowed to clot. The serum should 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 is needed but is not provided in the 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.

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

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

INTERFERENCE
1. Samples showing evidence of hemolysis should not be used.
2. Inhibitors of alkaline phosphatase activity include: oxalates, Hg^{++}, excess inorganic phosphate, bile acids, some amino acids and urea.
3. Lipemic samples >3+ should be ultra-centrifuged and the analysis performed on the infranate.
4. On this method, refer to the work of Young for a review of drug and comprehensive list of substances effect on Alkaline Phosphatase level.

EXPECTED VALUE
32-92 IU/L or 0.5 to 1.5 µkat/L

PROCEDURES:
Settings for TC-Matrix 160

Test Name:	ALP	R1:	164
Full Name:	Alkaline Phosphatase	R2:	35
Pri. Wave:	405 nm	Sample Volume:	2.0
Sec. Wave:	700 nm	Calibration Type:	2 point linear
Assay/ Point:	Kinetic	K Value:	/
Start - End:	14 - 21	Point:	2
Decimal place:	0	Blank Type:	Water
Unit:	U/L	Point 0 (Blank) Con.:	0.0
Linearity Range:	5.0000 - 1700.00	Point 1 (STD) Con.:	Standard/
Correlation Factor:	1.0000 - 0.0000		Calibrator

Settings for TC-Matrix 240

Test Name:	ALP	R1:	164
Full Name:	Alkaline Phosphatase	R2:	35
Pri. Wave:	405 nm	Sample Volume:	2.0
Sec. Wave:	700 nm	Calibration Type:	2 point linear
Assay/ Point:	Kinetic	K Value:	/
Start - End:	20 - 27	Point:	2
Decimal place:	0	Blank Type:	Water
Unit:	U/L	Point 0 (Blank) Con.:	0.0
Linearity Range:	5.0000 - 1700.00	Point 1 (STD) Con.:	Standard/
Correlation Factor:	1.0000 - 0.0000		Calibrator

PERFORMANCE CHARACTERISTICS

Analytical Range: 5-1700 IU/L

For Alkaline Phosphatase analyte by Alkaline Phosphatase Reagent on TC Matrix, this method has been demonstrated to be linear from 5-1700 IU/L.

Accuracy: Comparison study was performed on TC Matrix for 40 samples. Beckman Coulter Alkaline Phosphatase reagent was used to compare with Teco Alkaline Phosphatase Reagent. The results of this study yield a correlation coefficient of 0.99 with a regression equation of y = 0.99x +1.9.

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

Sample	Sample 1	Sample 2
N	25	25
Mean (IU/L)	95	330
Standard Deviation (IU/L)	3.8	9.7
Coefficient of Variation (%)	3.9	2.7

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

Sample	Sample 1	Sample 2
N	25	25
Mean (IU/L)	93	332
Standard Deviation (IU/L)	4.2	10.5
Coefficient of Variation (%)	4.0	2.9

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 Biosafety in Microbiological and Biomedical Laboratories manual, and in accordance with national or local regulations related to the safety precautions of such materials.
3. Each laboratory has to perform the quality control tests to ensure the results are reliable before testing the specimens.

REFERENCES:

1. Bowers GN, McComb RB and Kelley ML 1977. Measurement of total alkaline phosphatase activity in human serum. (in: selected Methods of clinical chemistry, G.R. Cooper, ED. AACC., Washington, Vol.8.)
2. Tietz NW, Weinstock A, Rodgerson D 1976. Selection of reaction conditions for the measurement of alkaline phosphatase activity. (in: Proc 2nd int. Symp Cli. Enzymol AACC, Washington D.C.)
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, 2nd 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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