diatron

ALKALINE PHOSPHATASE (ALP)

For use on Diatron Pictus® series analyzers
Method: IFCC
Product code: 1419-0132, 1419-0130
Package: 6 x 20 ml (R1) + 6 x 20 ml (R2), 6 x 11 ml (R1) + 6 x 11 ml (R2)
Store at: 2° – 8°C
For *in vitro* use only

INTENDED USE
Ready to use reagents for the quantitative determination of Alkaline Phosphatase (ALP) in human serum or plasma specifically for use with Diatron Pictus® series analyzers. For in vitro diagnostic use only.

CLINICAL SIGNIFICANCE
The origins of the major phosphatases are liver, bone, intestine, endometrium and lung. Ingestion of a meal increases the intestinal isoenzyme of ALP in serum. ALP activity increases in children during periods of rapid growth, in females in the last trimester of pregnancy, and after menopause. Increased levels of ALP are related to bone metabolism (ALP is increased in childhood or during the healing of a fracture), primary and secondary hyperparathyroidism, osteomalacia, and juvenile rickets. Moreover increased levels are observed at various bone diseases like metastatic carcinoma in bone, osteogenic sarcoma, myeloma, Hodgkin's disease if bones are invaded, Gaucher's disease with bone resorption, Paget's disease and Cushing's syndrome. Elevated levels of ALP are noted in liver diseases like infectious mononucleosis, uncomplicated extrahepatic biliary obstruction, cytomegalovirus infection in infants, cholangitis and cholangiolitis, hepatocellular jaundice, portal cirrhosis, primary hepatocellular carcinoma, secondary carcinoma, extrahepatic sepsis. ALP deficiency is observed in hypothyroidism, gross anemia, achondroplasia, hypophosphatasemia, deposition of radioactive elements on the bones, severe vitamin B_{12} deficiency, Kwashiorkor syndrome, and nutritional deficiency in zinc or magnesium.

METHOD PRINCIPLE
The determination of alkaline phosphatase according to the IFCC recommendations is based on the following reaction:

p-Nitrophelyl phosphate + H_20 $\xleftarrow{\text{ALP}}$ Phosphate + p-Nitrophenol

ALP: alkaline phosphatase

The rate of change of absorbance at 405/505 nm is proportional to ALP activity.

METHOD LIMITATIONS
Refer to the book "Effects of Preanalytical Variables on Clinical Laboratory Tests" for possible interference of other pharmaceutical agents in this particular test. Interference of other agents is described in the "Clinical Guide to Laboratory Tests".
The reagent is designed especially for use with the Diatron Pictus® series of chemistry analyzers. For chemistry protocols and further information please contact the customer support unit at Diatron.

REAGENT COMPOSITION
Reagent 1:

2-Amino-2-Methyl-1-Propanol (pH 10.4):	700 mM
HEDTA:	4.0 mM
Magnesium acetate:	4.0 mM
Zinc sulfate:	2.0 mM
Non reactive ingredients, preservative.	

Reagent 2:

p-Nitrophelyl phosphate:	32 mM
Non reactive ingredients, preservative.	

WARNINGS - PRECAUTIONS
- This reagent is designed for in vitro diagnostic use. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory techniques. Avoid inhalation and contact with eyes and skin.
- Samples should be considered as potentially infectious. Handle with special caution.
- This reagent contains sodium azide (NaN_3) ≤ 0.1%. Avoid swallowing and contact of the reagent with skin and mucous membranes.
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON HELLAS (manufacturer) upon request.

REAGENT PREPARATION
Reagents R1 and R2 are liquid and ready-to-use when placed in the corresponding positions on the analyzer. The vials bear barcodes for automatic recognition by Pictus® series analyzers.

REAGENT DETERIORATION
The reagents should not be used:
- When they do not exhibit the specified linearity or control values lie outside the acceptable range after recalibration.
- When they appear turbid.
- After prolonged exposure to sunlight or high temperature.

SHELF LIFE
Unopened, reagents are stable at 2 – 8°C up to the expiry date stated on the label. Once opened, they remain stable for 14 days when stored in the cooled reagent tray of the Pictus® series analyzers.

SAMPLE
Fresh non hemolyzed serum or heparinized plasma. Oxalate, citrate and EDTA form complexes and should be avoided. Fresh samples should be analyzed within 4 hours. Frozen samples should be allowed to come and remain at room temperature at least 18 – 24 hours before analysis, in order to recover full ALP activity. Avoid repeated freezing-thawing of samples.

CALIBRATION
Diatron provides MEDI-CAL (1578-0891) for calibration. Calibrate the assay when a new lot of reagent is installed. The analyzer will automatically perform a Reagent Blank measurement every 7 days. Calibration should be repeated when a new lot of reagent is used, after major maintenance is performed on the analyzer, after a critical part is replaced, or when a significant shift in control values occurs.

QUALITY CONTROL
Diatron provides Clinical Chemistry Control Level 1 & 2 (1578-0901-12 & 1578-0902-12 respectively) for serum quality control.
Control recovery should lie within the acceptable range. Results outside the acceptable range even after recalibration could be due to reagent deterioration, unsuitable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

MATERIALS REQUIRED BUT NOT SUPPLIED WITH THE KIT
- ALP calibrator
- Quality control materials.
- Diatron Pictus® P400/P700/P500
- Common laboratory equipment.

REFERENCE INTERVALS
Serum, plasma: 25 – 125 U/L (adults) < 500 U/L (teenagers)
Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practices.

WASTE DISPOSAL
This product contains sodium azide (NaN_3), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build up in the drain pipes.

SPECIFIC PERFORMANCE CHARACTERISTICS
The following values are representative of the reagent performance on Diatron Pictus® series analyzers. The reagent performance has been evaluated on other types of analyzers, covering all requirements of the 98/79 IVD Directive. A list of analyzers with the corresponding performance characteristics is available in the special leaflet accompanying the insert. The results taken in your laboratory may differ from these values.

	Pictus® P400	Pictus® P700/P500
Linearity	Up to 1500 U/L	Up to 1500 U/L
Lowest detection limit	4.8 U/L	13 U/L

The lowest detection limit (LDL) is defined as the lowest concentration of analyte that is distinguishable from zero. A sample free of analyte is assayed 20 times within the assay and the LDL is calculated as the absolute mean plus three standard deviations.
Precision: Precision is estimated on two concentration levels of analyte according to CLSI protocol EP-5T (20 consecutive days, 2 runs per day, 2 repeats per run).

Pictus® P400			Pictus® P700/P500		
Level (U/L)	Within Run CV%	Total CV%	Level (U/L)	Within Run CV%	Total CV%
121	3.40	3.96	114	2.69	3.44
460	2.37	3.03	372	2.09	2.97

Interferences: Criterion: recovery within ±20% from target value

	Pictus® P400	Pictus® P700/P500
Lipemia	Insignificant up to 1000 mg/dL Intralipid®	Insignificant up to 1000 mg/dL Intralipid®
Haemoglobin	Insignificant up to 500 mg/dL	Insignificant up to 500 mg/dL
Non conj. Bilirubin	Insignificant up to 15 mg/dL	Insignificant up to 15 mg/dL
Conj. Bilirubin	Insignificant up to 20 mg/dL	Insignificant up to 20 mg/dL
Ascorbate	Insignificant up to 3 mg/dL	Insignificant up to 3 mg/dL

Correlation: A comparison was performed between this reagent on a Pictus® series analyzer, and a BECKMAN COULTER AU-series systtem. The results were as follows:

Pictus® P400
Y = 0.964X – 0.735 R=0.9960 N=30 Sample range = 50.0 – 203 U/L
Pictus® P700/P500
Y = 0.998X + 12.96 R=0.9960 N=40 Sample range = 40.2 – 218 U/L

BIBLIOGRAPHY

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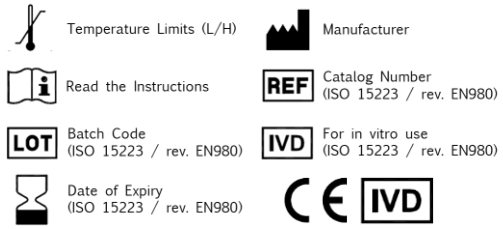
3. Jacobs, DJ, Demott, WR, Grady, HJ, Horvat, RJ, Huestis, DW and Kasten, BL, JR, eds. Laboratory Test Handbook. 4th. ed. Ohio, Hudson: Lexi-Comp Inc., 1996.
4. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd. ed. Washington, DC: The American Association for Clinical Chemistry Press, 1997.
5. Bowers, GN, Mc Comb, RB. Measurement of Total Alkaline Phosphatase Activity in Human Serum. Clin. Chem. 1975: 21; 1988-1995.
6. Tietz, NW, Rinker, AD, Shaw, LM. IFCC Methods for the Measurement of Catalytic Concentration of Enzymes. Part 5. IFCC Method for Alkalin Phosphatase. J.Clin.Chem.Clin.Biochem. 1983: 21; 731-748.

SYMBOLS ON THE LABEL


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