ALKALINE PHOSPHATASE (ALP)

Specifically for use with Diatron PICTUS® 700 and PICTUS® 500 Analyzers

REF 1419-0130 **Packaging:** 6 x 11 ml (R1) + 6 x 11 ml (R2)

2°C 8°C

Σ 660

INTENDED USE

Reagents for In Vitro quantitative automated determination of Alkaline Phosphatase - ALP (EC 4.1.2.13) in samples of human serum or plasma from the general patient population. Measurements of Alkaline Phosphatase are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid for diagnosis of bone metabolism diseases and other disorders with bone involvement.

This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers.
For in vitro diagnostic use only by trained laboratory professionals.

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 B12 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_2O $\xrightarrow{\text{ALP}}$ Phosphate + p-Nitrophenol

ALP: alkaline phosphatase

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". This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers. For additional information please contact customer support at Diatron or Medicon.

REAGENT COMPOSITION

Reagent R1	Reagent R2
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.	p-Nitrophelyl phosphate: 32 mM Non-reactive ingredients, preservative.

⚠ **WARNINGS – PRECAUTIONS**

- The 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.
- Avoid swallowing and contact of the reagent with skin and mucous membranes.
- Dispose all waste according to national laws.
- Any serious incident that may occur in relation to this device must be reported by the user to the manufacturer and the competent authority of the country in which the user and/or the patient is established!
- MSDS is available by Diatron and MEDICON upon request.

⚠ **PREPARATION**

Reagent ready to use when placed in the corresponding position on the analyzer. The vials bear barcodes for automatic recognition by Diatron Pictus® P700 / P500 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 2 weeks when stored in the cooled reagent tray of the Diatron Pictus® P700 or P500 analyzers.

⚠ **SAMPLE** Serum or Li-heparin plasma can be used as specimen. Use established Good Laboratory Practices for sampling, transport and separation from blood cells. Do not use hemolyzed, contaminated or turbid sample specimens. Anti-coagulants other than Li-heparin have not been tested and should not be used. Centrifuge sample as soon as possible, separate serum or plasma from blood cells and store properly if analysis cannot take place right after sample separation. Alkaline Phosphatase is stable in serum samples for 4 hours in room temperature, for 7 days when stored at 2 – 8°C, and up to 2 months when stored at –20°C. Frozen samples should be allowed to reach and remain at room temperature at least 18 – 24 hours before analysis, in order to recover full ALP activity. Mix carefully thawed samples before analysis. Do not freeze thawed samples.

CALIBRATION Diatron offers MEDICON MEDI-CAL (1578-0891) traceable to Medicon Master Lot, for calibration. Calibrate the assay when a new lot of reagent is installed. The analyzer will automatically perform a Reagent Blank measurement every 1 week. 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 offers MEDICON 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 PROVIDED WITH THE KIT

- ALP calibrator
- Quality control material
- Diatron Pictus® analyzer
- 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 (NaN3), 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® P700 or P500 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.

Linearity Up to 1500 U/L

Lowest detection limit 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).let accompanying the insert. The results taken in your laboratory may differ from these values.

Pictus® P700 and P500	
Level (U/L)	**Within Run CV%**
56.0	1.80
386.0	2.40
Level (U/L)	**Total CV%**
56.0	2.70
386.0	4.20

INTERFERENCES - Criterion: recovery within ±10% from target value

	(Insignificant up to)
Triglycerides	3000 mg/dL
Hemoglobin	500 mg/dL
Bilirubin	15 mg/dL
Conj. Bilirubin	20 mg/dL
Ascorbate	3 mg/dL

Correlation: A comparison was performed between this reagent on a Diatron Pictus® P700 and P500 analyzer and another commercially available product. The results were as follows:

Y = 0.998X + 12.96 R=0.9960 N=40 Sample range = 40.2 – 218 U/L

BIBLIOGRAPHY

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SYMBOLS

Manufacturer

IVD *In vitro* diagnostic medical device

Temperature Limit

REF Catalogue Number

Caution

Σ Contains sufficient for <n> tests

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