ALKALINE PHOSPHATASE SYSTEM PACK

Unicorn 480, Bonavera Chem 480 & Bonavera Chem 400

(Fully Auto Biochemistry Analyzer)

BEACON

Code	Product Name	Pack Size
UNI03	Alkaline Phosphatase System Pack	4 x40 + 4 x10 ml

INTENDED USE

Diagnostic reagent for quantitative *in vitro* determination of ALP in human serum or plasma.

CLINICAL SIGNIFICANCE

Human ALP consists of a group of enzymes which hydrolyse phosphates at an alkaline pH. ALP is found in practically all tissues of the body but in high concentrations in the osteoblasts of bone, liver, placenta, kidney, intestinal wall and lactating mammary glands. In adults the ALP normally found circulating in the serum is largely derived from the liver. In children or in adolescents going through pubertal growth spurts, these is an additional contribution from bone and this accounts for the higher reference interval for these groups. Pregnancy also raises the normal values of ALP.

Raised ALP levels are often observed in bone disease or liver disease involving the biliary tract. If the source of the isoenzyme is not apparent then estimation of GGT may help differentiate between the two. A raised GGT in the presence of a raised ALP would suggest the liver is the primary source.

Increased ALP (usually normal GGT) is seen in Osteomalacia and Rickets, primary hyperparathyroidism with bone involvement, Pagets disease, secondary carcinoma in bone and some cases of osteogenic sarcoma. Increased levels of ALP (usually with a raised GGT) is seen in cholestasis, hepatitis, cirrhosis, space occupying lesions and malignancy with bone or liver involvement or direct production. Low levels of ALP may be observed in conditions which cause arrested bone growth or in hypophosphatasia.

PRINCIPLE

The method according to IFCC recommendation. This method utilises 4-nitrophenyl phosphate as the substrate. Under optimised conditions ALP present in the sample catalyses the following reaction.

$$\text{AMP} + \text{4-NNP} + H_2O \xrightarrow[Mg^{2+}/\text{Alkaline pH}]{\text{ALP}} \text{4-nitrophenol} + \text{phosphate}$$

At the pH of the reaction, 4-nitrophenol has anintense yellow colour. The reagent also contains a metal ion buffer system to ensure that optimal concentrations of Zinc and Magnesium are maintained. The metal ion buffer can also chelate other porentially inhibitory ions which may be present. The reaction is monitored by measuring the rate of increase in absorbance at 405 or 415 nm which is proportional to the activity of ALP in the serum.

REAGENT COMPOSITION

Reagent 1 : Alkaline phosphatase buffer Reagent

2-AMP	>250 mmol/L
Mg+2	>2 mmol/L
Zn+2	<10 mmol/L
HEDTA	>1.5 mmol

Reagent 2 : Alkaline Phosphatase Substrate Reagent

p-nitrophenyl phosphate	>16 mmol

REAGENT PREPARATION

Ready to use

STABILITY AND STORAGE

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2–8°C.

On board stability: Min. 15 days if refrigerated (2-10°) and not contaminated.

SPECIMEN COLLECTION AND HANDLING

Use serum, plasma (Heparin).

It is recommended to follow NCCLS procedures (or similar standardized conditions).

Stability in serum / plasma:

4 hours	at 20–25°C
3 days	at 4–8°C
2 months	at -20°C

Discard contaminated specimens.

CALIBRATION

Calibration with the Beacon Multicalibrator is recommended.

QUALITY CONTROL

It's recommended to run normal and abnormal control sera to validate reagent performance

UNIT CONVERSION

U/l x 0.017 = µkat/l

EXPEXTED VALUES

Children (3-15 yrs) : 104 - 309 U/L
Adults : 25 - 140 U/L

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

PERFORMANCE DATA

Data contained within this section is representative of performance on Beacon. Data obtained in your laboratory may differ from these values.

Limit of quantification: 10.0 U/L
Linearity: 1200 U/L
Measuring range: 10.0 – 1200 U/L

Intra-assay precision Within run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	83	1.60	1.92
Sample 2	399	5.24	1.31

Inter-assay precision Run to run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	95	0.65	0.69

COMPARISON

A comparision between Alkaline Phospahatse System Pack (y) and commercially available tests (x) using 40 samples gave following results:

y = 1.006x - 1.119 U/l
r = 0.998

INTERFERENCES

Following substances do not interfere:
haemoglobin up to 5 g/l, bilirubin up to 40 mg/dl, triglycerides up to 2000 mg/dl.

WASTE MANAGEMENT

Please refer to local legal requirements.

Parameter for Unicorn 480, Bonavera Chem 480 &

Bonavera chem 400 (Fully Auto Biochemistry Analyzer)

TEST NAME	ALKALINE PHOSPHATASE
FULL NAME	ALKALINE PHOSPHATASE
PRI WAVE	405 nm
SEC WAVE	630 nm
ASSAY/POINT	KINETIC
START	16
END	33
DECIMAL	2
UNIT	U/L
LINEARITY RANGE LOW	10
LINEARITY RANGE HIGH	1200
SAMPLE VOLUME	4 µ l
REAGENT 1 (R1) VOLUME	160 µl
REAGENT 1 (R2) VOLUME	40 µl
SUBSATRATE DEPLETED	-
LINEARITY	1200 U/L
OUT OF LINEARITY RANGE	-
CALIBRATION TYPE	2 Point linear
POINTS	2
BLANK TYPE	Reagent
CONCENTRATION BLANK	0.00
CONCENTARTION STD	Refer calibrator value sheet.
SAMPLE VOLUME	4 µ l

NOTE

The program is made as per the in house testing, it can be modified as per requirements.

REFERENCES

1. Zilva JF, Panall PR, “Plasma Enzymes in Diagnosis” in Clinical Chemistry in Diagnosis and Treatment. Lloyd London 1979: Chapter 15 : 343.
2. IFCC method for the measurement of ALP J. Clin. Chem. Clin. Biochem. 1983: 21: 731-48.
3. Young DS. Effects of Drugs on Clinical Laboratory Tests. Third Edition 1990 : 3 : 19.25.
4. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. Burtis, C.A., Ashwood, E.R., Bruns, D.E.; 5th edition, WB Saunders Comp., 2012.
5. Kaplan and Pesce (Eds.) Clinical Chemistry, Theory analysis and correlation. Second Edition. CV Mosby Co. 1989.

IVD

SYMBOLS USED ON LABELS

REF Catalogue Number

Manufacturer

See Instruction for Use

LOT Lot Number

CONT Content

Storage Temperature

Expiry Date

IVD In Vitro Diagnostics

BEA/24/ALP/UN/IFU-01 DATE :25/08/2023