CRESCENT DIAGNOSTICS

ALKALINE PHOSPHATASE
KINETIC-DGKC METHOD

CE IVD

REF	DESCRIPTION
CZ901U	ALKALINE PHOSPHATASE

PACKAGE SIZES

CZ901U-1	50 ml	CZ901U-4	10 X 100 ml
CZ901U-2	100 ml	CZ901U-5	2 X 500 ml
CZ901U-3	10 X 20 ml	CZ901U-6	5 L

INTENDED USE

This reagent is intended for *in vitro* quantitative determination of Alkaline Phosphatase (ALP) in serum or plasma.

INTENDED USER: Professional Use Only**.**

METHOD

KINETIC-DGKC METHOD

CLINICAL SIGNIFICANCE

Alkaline Phosphatase (ALP) is widely distributed throughout the body, but clinically important one for diagnostic reasons is in bone, liver, placenta & intestine. Growing bone is associated with the release of ALP and so in childhood the level of ALP is around 3 times of that of adult. During pregnancy in 2nd & 3rd trimester the enzyme rises considerably due to placenta releasing ALP. It can be used to examine placental function.
Elevated levels are seen in bone diseases, e.g. Paget's disease, rickets, osteoplastic metastatic & in obstructive disease of biliary tract.
Decreased levels are rarely seen. E.g. in Vitamin A resistant rickets.

PRINCIPLE

Alkaline Phosphatase (ALP) catalyses the hydrolysis of P-Nitrophenyl phosphate (p-Npp) at pH 9.8, liberating p-Nitrophenol and phosphate, according to the following reaction:

$$\text{p-Npp} + H_2O \xrightarrow{\text{ALP}} \text{P-Nitrophenol} + \text{Phosphate}$$

The rate of p-Nitrophenol formation, measured photometrically, is proportional to the catalytic concentration of alkaline Phosphatase present in the sample

REAGENT COMPOSITION

ALP BUFFER R1

Diethanolamine	1.0 mol/l
Magnesium chloride	0.5 mmol/l

ALP SUBSTRATE R2

P-Nitrophenylphosphate	10 mmol/l

REAGENT PREPARATION

SUBSTRATE START

R1 and R2 are ready-to-use and stable until expiry date if contamination is avoided and stored at 2-8°C

SAMPLE START

Mix 4 parts of R1 + 1 Part of R2 = Mono reagent
Stability of mono reagent: 4 Weeks at 2-8°C, 5 days at 15-25°C

SPECIMEN

Serum, heparinized plasma

PRECAUTION

1- The reagents contain sodium azide as preservative. Do not swallow and avoid contact with skin and mucous membranes.
2- During the reaction P-Nitrophenol is produced. This is poisonous when inhaled, swallow or when absorbed through skin. If the reaction mixture comes in contact with skin or mucous membranes wash copiously with water.
3- To avoid contamination, use clean laboratory wares. Avoid direct exposure of reagent to light.

ASSAY

Wavelength	:	405 nm
Cuvette	:	1 cm light path
Temperature	:	25°C/ 30°C/37°C
Measurement	:	Against reagent blank

PROCEDURE

SUBSTRATE START

Reagent 1 Buffer	1000 µL
Sample	20 µL
Mix incubates for approx... 1 min, then add	
Reagent 2 Substrates	250 µL

SAMPLE START

Mono reagent (R1+R2)	1000 µL
Sample	20 µL

READING FOR BOTH

Mix and read absorbance after 1 min and start stop watch.
Read absorbance again after 1, 2, 3 min.

CALCULATION

SUBSTRATE START

ALP activity U/L = ΔA/min. X 3433

SAMPLE START

ALP activity U/L = ΔA/min. X 2757

LINEARITY

The reagent is linear upto 700 U/L
If the activities exceed 700 U/L, mix 50 µL of sample with 200µL of 0.9% NaCl solution and multiply the result by 5.

NORMAL RANGE

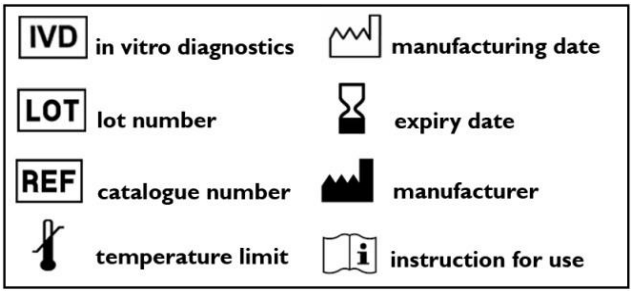
	25°C	30°C	37°C
Women U/L	40-190	48-223	64-306
Men U/L	50-190	60-223	80-306
Children up to 15 years U/L, up to	400	488	644

Each laboratory should establish reference ranges for its own patients population.

QUALITY CONTROL

All control sera with values determined by this method can be used.

SYMBOL ON LABELS



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CZ901U-ALP
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EC REP

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