

TRUEchemie ALKALINE PHOSPHATASE TEST KIT(SR)

(IFCC)



for the quantitative determination of Alkaline Phosphatase concentration in serum or plasma

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INTENDED USE

The TRUEchemie ALP test kit is for the quantitative determination of ALP concentration in human serum or plasma.

INTRODUCTION

Alkaline Phosphatase (ALP) belongs to the Hydrolase class of enzymes and catalyses the splitting of organic phosphate esters, with optimum activity at pH 10.20 is ubiquitously distributed throughout the body. However, liver, bone and placenta contain very high concentrations of ALP. Hence, increase in ALP activity is usually related to hepatobiliary and bone disorders. Elevated ALP levels are seen in toxic hepatitis, infective hepatitis, intra and extra hepatic obstructions. High ALP levels are also seen in osteomalacia, rickets and bone Cancer. The use of p-Nitrophenyl Phosphate (p-NPP) as a substrate for ALP assay produces a chromogenic product, p-Nitrophenol (PNP) which is quantified directly.

PRINCIPLE



PACK SIZE

| Kit Size | 1 x 50 ml | 2 x 50 ml | 2 x 500 ml |
|----------------|-----------|-----------|------------|
| Cat. No. | ADX 201 | ADX 202 | ADX 203 |
| Kit Contents | | | |
| 1) ALP Reagent | 1 x 50 ml | 2 x 50 ml | 2 x 500 ml |

REAGENT COMPOSITION

| | |
|--|--------------|
| 2-Amino-2-methyl-1-propanol buffer pH 10.4 | 0.70 mmol/L |
| p-Nitrophenylphosphate | 12.00 mmol/L |
| HEDTA | 1.55 mmol/L |
| Mg Acetate | 1.50 mmol/L |
| Preservatives and stabilizers | |

STORAGE AND STABILITY

The components of the kit, stored at 2 - 8 °C, will remain stable until the expiry date stated on the label.

REAGENT PREPARATION

Ready to use reagents.

SAMPLE / SPECIMEN AND STORAGE

Serum or heparinized plasma.
Use samples free from hemolysis. Serum kept in the refrigerator at 2-8 °C will remain stable for 7 days.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Specimens should be considered infectious and handled appropriately.
- Avoid ingestion. DO NOT PIPETTE BY MOUTH.
- The reagent contains sodium hydroxide that is corrosive. In case of contact with skin, flush with water. For eyes, seek medical attention.
- The disposal of the residues has to be done as per local legal regulations.

MATERIALS REQUIRED BUT NOT PROVIDED

- Pipettes to accurately measure required volumes.
- Test tubes/rack
- Timer
- 37 °C heating block or water bath
- Photometer capable of accurately measuring absorbance at 405 nm

TEST PROCEDURE

Primary wavelength 405 nm
Temperature 37 °C
Prewarm the Reagent to reaction temperature.

| | Blank (ml) | Sample (ml) |
|-----------------|------------|-------------|
| Distilled water | 1.000 | -- |
| ALP Reagent | -- | 1.000 |
| Sample | -- | 0.025 |

Mix & take the first reading after 30 Sec. and take THREE additional readings at 60 Sec. intervals. Calculate mean absorbance change per minute ($\Delta A/\text{min.}$)

Calculations

Determine the $\Delta E/\text{min.}$ for every reading and find the mean value.
Calculate the U/L from:
 $(\Delta E/\text{min.}) \times 2757 = \text{U/L}$

NORMAL VALUES

Adults Women: 42 – 141 U/L
Men: 53 – 128 U/L

It is strongly recommended that each laboratory establish its own normal range

QUALITY CONTROLS

Control Sera are recommended to monitor the performance of manual and automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions

AUTOMATED PROCEDURE

Appropriate program sheet is available for different analyzers upon request.

LIMITATIONS OF TEST

Linearity : 650 U/L ALP.

Samples that have ALP values greater than 650 U/L should be diluted with saline water (NaCl 0.9 %) 1:1, re-assayed and the results multiplied by 2.

INTERFERENCES

- Hemolysis and lipemia will interfere the assay.
- Anticoagulants such as EDTA, oxalate or citrate which chelate divalent cations should not be used since they would result in enzyme inhibition.

SYSTEM PARAMETERS

| | | |
|-----------------|---|--------------------|
| Mode | : | Kinetic |
| Factor | : | 2757 |
| Wave length | : | 405 nm |
| Units | : | U/L |
| Flow cell Temp. | : | 37 °C |
| Blank | : | Distilled water |
| Reagent volume | : | 1000 μL |
| Sample volume | : | 25 μL |
| Lag time | : | 30 Sec. |
| Read time | : | 180 Sec. |
| Low Normal | : | 42.00 |
| High Normal | : | 141.00 |

REFERENCES

- Szasz, G., Rautenburg, H.W. (1971). Z. Kinderheilk., 111, 233 - 239. George N., Bowers Jr, and Rober B., (1975). Clin. Chem., vol 21; N° 13.
- Measurement of Total Alkaline phosphatase activity in human serum. Tietz N.W., Rinker D., Shaw L.M. (1983).
- IFCC methods for the measurement of catalytic concentrations of enzymes. Part 5: IFCC method for Alkaline phosphatase. J. Clin. Chem. Clin. Biochem.; 21, 731 - 748.
- Soldin J.S., Brugnara, C., Wong, E.C., (2003). Pediatric references ranges. Washington AACC Press; p.10.

Index of Symbols

| | | |
|---|------------------------|----------------------------------|
| Consult instructions for use | Catalogue number | Use-by date |
| For <i>in vitro</i> diagnostic use only | Batch code | Do not use if package is damaged |
| Temperature limit 2-8 °C | Date of manufacture | Keep dry |
| Keep away from sunlight | Manufacturer | European Conformity |
| If device is non-sterile | Warnings / Precautions | Authorized Representative |