

**INTENDED USE**

The TRUEchemie Alkaline Phosphatase Test Kit (SR - IFCC) is used 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**

<b>Kit Size</b>	1 x 50 ml	2 x 50 ml
<b>Cat. No.</b>	ADX201	ADX202
<b>Kit Contents</b>		
1) ALP (SR) Reagent	1 x 50 ml	2 x 50 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	

**REAGENT PREPARATION**

Ready to use reagents.

**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.

**REAGENT STORAGE & STABILITY**

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2-8°C. Do not use reagents over the expiration date.

**SPECIMEN COLLECTION 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.

**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 (µL)	Sample (µL)
Distilled water	1000	--
ALP (SR) Reagent	--	1000
Sample	--	25

Mix & take the first reading after 30 Sec. and take THREE additional readings at 60 Sec. intervals. Calculate mean absorbance change per minute (ΔA/min.)

**Calculations**

Determine the ΔE/min. for every reading and find the mean value.

Calculate the U/L from:

(ΔE/min.) x 2757 = U/L

**QUALITY CONTROL**

Quality Controls are recommended to monitor the performance of automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

**EXPECTED VALUE**

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

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

**PERFORMANCE CHARACTERISTICS**

Sensitivity: 2.0 U/L  
Linearity: 650 U/L under the described assay conditions. If the concentration is greater than linearity (650 U/L), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor. The linearity limit depends on the sample / reagent ratio, as well as the analyzers used.

**PRECISION:**

Intra-assay precision within run (n=10)	Mean (U/L)	SD (U/L)	CV (%)
Control Level - 1	98.9	0.7	0.7
Control Level - 2	400.8	0.5	0.1
Inter-assay precision run to run (n=12)	Mean (U/L)	SD (U/L)	CV (%)
Control Level - 1	103.8	0.6	0.6
Control Level - 2	400.9	0.4	0.1

The reagent was tested for 12 days, using two different ALP concentrations. The coefficient of variation was <5%.

**AUTOMATED PROCEDURE**

Appropriate program sheet is available for different analyzers upon request.

**METHOD COMPARISON**

Results obtained using TRUEchemie ALP reagent (y) did not show systematic differences when compared with another commercial reagent (x) with similar characteristics. The results obtained is below: The correlation coefficient (r<sup>2</sup>) was 0.997 and the regression equation is y=0.973x+5.77. The results of the performance characteristics depend on the analyzer used.

**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.

**WASTE MANAGEMENT**

Please refer to local regulation requirements.















**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
Sensitivity	:	2.0
Linearity	:	650
Reaction Slope	:	Increasing

**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.
- ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

**Index of Symbols**

 Consult instructions for use	 Catalogue number	 Caution
 <i>In vitro</i> diagnostic medical device	 Batch code	 Non-sterile
 Temperature limit 2-8°C	 Do not re-use	 Use-by date
 Manufacturer	 Date of manufacture	 Keep dry
 Do not use if package is damaged		 Keep away from sunlight



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