ALKALINE PHOSPHATASE KIT

p-NPP Kinetic Method (IFCC Formulation)

Product Code: 10004	**Reaction Type:** Kinetic with Factor
Pack Size: 10 x 5 ml	**Matrix Target:** Human Serum & Plasma
Storage Temp: 2-8°C (Unopened Reagents)	**Wavelength:** 405 nm (Light Path: 1 cm)

INTENDED USE & CLINICAL SIGNIFICANCE

Intended Use: This liquid diagnostic reagent system is configured for the quantitative in vitro kinetic determination of Alkaline Phosphatase (ALP) activity in human serum or plasma specimens.

Clinical Significance: Alkaline Phosphatase is an enzyme found in high activity within the liver, biliary tract epithelium, and bones. Elevated ALP levels are characteristically observed in hepatobiliary diseases, biliary obstructions, drug-induced hepatotoxicity, osteomalacia, and bone malignancies. Diagnostic profiles must correlate with additional clinical findings.

METHOD PRINCIPLE

This formulation is based on the standardized IFCC method. Alkaline phosphatase hydrolyzes p-Nitrophenyl phosphate at an alkaline pH to release yellow-colored p-nitrophenol (p-NP):

> p-Nitrophenyl phosphate + H_2O → [Alkaline Phosphatase] → p-Nitrophenol (Yellow) + Phosphate

The rate of reaction is monitored photometrically by measuring the continuous rate of increase in optical density/absorbance at 405 nm. The rate of increase (ΔA/min) is directly proportional to the absolute catalytic activity of ALP in the sample.

STEP 1: REAGENT CONFIGURATION & PIPETTING BASELINE

Working Reagent Preparation: Reconstitute R1 (p-NPP substrate vial) with R2 (Buffer Solution) as stated on the vial. The reconstituted working reagent is stable for 10 days when stored at 2-8°C. Bring reagent to RT before running the test.

Reagent/Component Line	Test Vector Volume
Reconstituted Working Reagent (RT)	1000 µl
Patient Serum / Plasma Sample (Free from hemolysis)	20 µl

STEP 2: CALCULATIONS & DATA TRACKING

Operational Directive: Mix well and record the initial absorbance after exactly 30 seconds (A_0). Repeat the absorbance readings every 60 seconds up to 3 minutes (total 4 readings), capturing the progression. Determine the mean absorbance change per minute (ΔA/min):

$$\Delta A/min = (A_3 - A_0) / 3$$

Calculate the final serum ALP activity using the standardized mathematical system factor (2742):

$$\text{Serum ALP Activity (U/L)} = \Delta A/min \times 2742$$

TECHNICAL PARAMETERS & CLINICAL SUPPORT MATRIX

Universal Safeguards	For professional in vitro diagnostic use. Contains less than 0.1% sodium azide. Avoid gross hemolysis; ruptured red blood cells falsely alter baseline parameters. Utilize separate micro-pipette tips to eliminate cross-contamination.
Expected Range	**Adults:** 30–90 U/L (at 30°C) | 40–120 U/L (at 37°C) **Children (≤15 yrs):** <250 U/L (at 30°C) | <350 U/L (at 37°C)
Analytical Linearity	Linear up to 900 U/L. If ΔA/min exceeds 0.35, dilute 1 part of the sample with 9 parts of isotonic saline, re-assay, and multiply the calculated output by a dilution factor of 10.

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