

Alkaline Phosphatase (ALP) Test Kit (IFCC Method)

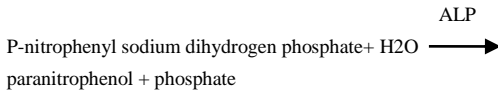
【NAME】

Alkaline Phosphatase (ALP) Test Kit (IFCC Method)

【INTEND USE】

This reagent is intended for the in vitro quantitative determination of Alkaline Phosphatase (ALP) in human serum, plasma.

【METHODOLOGY】



【STABILITY AND STORAGE】

Unopened, avoid light preservation in 2~8 °C, valid for 12 months;

Opened, avoid light preservation in 2~8 °C, valid for 1 month.

Reagent is not allowed frozen.

【SPECIMEN COLLECTION AND HANDLING】

It is best to fresh serum or plasma heparin. Don't use EDTA anticoagulant blood plasma. Do not use hemolysis sample.

【APPLICABLE INSTRUMENT】

Fully automatic biochemical analyzer.

【SYSTEM PARAMETERS】

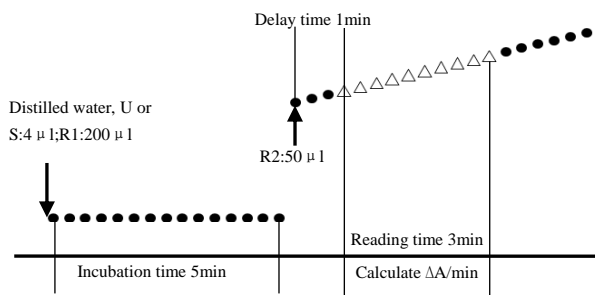
The following system parameters are recommended. Individual instrument applications are available upon request from the Technical Support Group.

Temperature	37° C
Cuvette light path	1.0cm
Primary Wavelength	405 nm
Secondary Wavelength	600nm
Assay Type	Rate method
Direction	Increase
Sample : Reagent Ratio	2:100:25
eg : Sample Vol.	4 μL
Reagent1 Vol.	200 μL
Reagent2 Vol.	50 μL
Linearity	0~550 U/L
Testing	Deducting the reagent blank

【OPERATIONG STEPS】

Double reagent operation:

R1:Reagent 1 R2:Reagent 2 S:Calibrator U:Sample



【CALCULATION】

Use the Calibrator

$$\text{Sample Concentration} = \frac{\text{Sample } \Delta\text{Abs}/\text{min}}{\text{Calibrator } \Delta\text{Abs}/\text{mi.}} \times \text{Calibrator Concentration}$$

【REFERENCE RANGE】

45~135U/L

By clinical trials, choose no less than 100 women or men blood specimens, tested by automatic biochemical analyzer, and then processing the testing value with statistical method, calculating out the reference range.

Recommendation: The laboratory set up its own reference range!

【THE LIMITATION OF TEST RESULTS】

ALP testing is just one of the standard that clinician diagnose the patient. Clinical physicians should according to patients' bodies, history and other diagnostic program, to get comprehensive judgment.

【THE INTERPRETATION OF TEST RESULTS】

Human error, the processing of specimen, analysis instrument deviation, etc. all can affect the measurement result; When one sample deviates from the expected value too far, need to be tested again.

【PERFORMANCE INDEX】

- 1.Reagent blank absorbance ≤ 0.8, (405nm, 1cm optical path).
- 2.Precision: repeatability CV ≤ 5%; batch variations R ≤ 5%.
- 3.Accuracy: relative deviation ≤ 10%.
- 4.Linearity range: 0~550U/L, r ≥ 0.990.
- 5.Stability: All package reagent, unopened and avoid light, preservation in 2~8 °C, stable 12 months, once opened, avoid light, preservation in 2~8 °C, stable 30 days.

【ATTENTION】

- 1.Reagent contains sodium azide (toxic) preservatives, avoid contact with skin and mucous membrane. If necessary preventive measures should be taken use of reagents, reagent contact with skin and mucous membrane, please rinse with water, please go to a doctor if necessary.
- 2.The maximum linearity is 550U/L. If testing results is upper limit, dilute with 0.9% sodium chloride solution before test, results multiplied by the dilution ratio.
- 3.Liquid waste disposal: Suggest follow local regulations
- 4.Different batches reagents cannot mix, when replacing reagents batch number, please calibration again.