Pariksha Biotech
A game changer in IVD

ALP Estimation Kit

# High-Q Alkaline Phosphatase-ML

IFCC-AMPD Buffer Method

HIGH® Command on Quality

**Intended Use:**

In vitro test for the quantitative determination of alkaline phosphatase (ALP) in human serum.

**Clinical Significance**

Alkaline phosphatase in serum consists of four structural genotypes: the liver-bone-kidney type, the intestinal type, the placental type and the variant from germ cells. It occurs in osteoblasts, hepatocytes, kidneys, spleen, placenta, prostate, leukocytes and the small intestine. The liverbone-kidney type is particularly important. A rise in the Alkaline Phosphatase activity occurs with all forms of cholestasis, particularly with obstructive jaundice. It is also elevated in diseases of the skeletal system, such as Paget`s disease, hyperparathyroidism, rickets and osteomalacia, as well as with fractures and malignant tumors. A considerable rise in the Alkaline Phosphatase activity is sometimes seen in children and juveniles. It is caused by increased osteoblast activity following accelerated bone growth. Various reference values for the purposes of clinical evaluation have been assigned to differing age groups. In 1946, Bessey, Lowry and Brock published a method for the determination of Alkaline Phosphatase using p-nitrophenyl phosphate as substrate buffered with glycine/NaOH. This assay described here meets the IFCC recommendations and uses AMP buffer.

**PRINCIPLE :**

p-Nitrophenyl Phosphate Analogue + $H_2O$ $\xrightarrow{ALP}$ p-Nitrophenol + phosphate

**Active Ingredients of reagents:**

| | | |
|---|---|---|
| AMP | pH 9.7 | 3.5 Mol/l |
| Magnesium chloride | | 0.6 mMol/l |
| p-Nitophenylphosphate Analogue | | 0.070 mMol/l |
| Sodium Azide | | 0.10 % |
| Zinc Sulphate | | 0.3 mMol/l |

**Reagent Storage and Stability**

1. When the reagent is stored properly at 2-8°C and the contamination is avoided, it is stable up to the expiry date mentioned on the labels and kit box.
2. It is recommended that when the reagent is not in use, it should be strictly kept at 2-8°C for better performance and stability.
3. Substrate Reagent must be protected from direct sun light.
4. Do not expose the reagent to high temperatures above 10°C.

**Specimen**

1. Unhemolysed serum is the preferred specimen. DO NOT USE PLASMA
2. Serum samples are stable for 24 hours at 2-8°C and for a month at -20°C. Please note that ALP activity in serum stored at 2-8°C increases with time.

**Test Procedure:**

High-Q Alkaline Phosphatase is a Mono Liquid Reagent and is ready to use . There is no reconstitution required.

**Test Procedure:**

| | |
|---|---|
| Substrate Reagent | 500 µl |
| Serum | 25 µl |

Mix well and aspirate in to the analyzer. After 20 Sec incubation (Delay) measure the change of optical density during the next 90 seconds (Measuring Time) against distilled water at 405 nm as follows.

| | |
|---|---|
| Ao- | Exactly after 20 Seconds. |
| A1 | Exactly after 90 seconds |

**Calculation**

Calculate the average change in absorbance per minute (△ A/min) and multiply by the corresponding factor.

ALP activity [IU/L]: △A/min x **5500**

**SYSTEM PARAMETERS:**

| | | |
|---|---|---|
| REACTION TYPE (MODE) | : | KINETIC |
| REACTION DIRECTION | : | INCREASING |
| WAVE LENGTH | : | 405 NM |
| FLOW CELL TEMP. | : | 37°C |
| ZERO SETTING WITH | : | DISTILLED WATER |
| DELAY TIME | : | 20 SECONDS |
| MEASURING TIME | : | 90 SECONDS |
| REAGENT VOLUME | : | 500 µl |
| SAMPLE VOLUME | : | 25 µl |
| FACTOR | : | **5500** |
| LINEARITY | : | 1250 |
| UNITS | : | IU/L |

**Expected Values:**

As per the recommendations of International Liver Foundation the following reference values are assigned for ALP IFCC Assays. But it is for the Laboratory to establish its own reference values.

**Reference Range:**

**Adults :**

| | | |
|---|---|---|
| **Men** | **[IU/L]** | **40 - 130** |
| **Women** | **[IU/L]** | **35 - 105** |

**Children:**

| | | |
|---|---|---|
| **1-30 Days** | **[IU/L]** | **48-406** |
| **1 Month- 1 Year** | **[IU/L]** | **124-341** |
| **1 Year- 3 Years** | **[IU/L]** | **108-317** |
| **4 Years- 6Years** | **[IU/L]** | **96-297** |
| **7 Years- 9 Years** | **[IU/L]** | **69-325** |
| **10 Years- 12 Years** | **[IU/L]** | **51-332** |
| **13 Year- 15 Years** | **[IU/L]** | **50-162** |
| **16 Year- 18 Years** | **[IU/L]** | **47-119** |

**Specificity /Interference**

No interference is absorbed by triglycerides up to 2200 mg/dl, bilirubun up to 42 mg/dl, hemoglobin up to 150 mg/dl, intra lipids up to 1200 mg/dl and ascorbic acid up to 32 mg/dl

**Sensitivity**

The lower limit of detection is 2 IU/L

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**Performance Characteristics:**
**Linearity - Measuring Range**

## 1250 IU/L

The test has been developed to determine Alkaline Phosphatase activities which correspond to maximal A/min of 0.227

If such value is exceeded the sample should be diluted 1+9 with NaCl solution (9g/l) and the results be multiplied by 10.

**Precision**

| Intra-assay precision | mean | SD | CV |
|---|---|---|---|
| N=20 | (IU/L) | (IU/L) | (%) |
| Sample 1 | 143.1 | 2.30 | 1.59 |
| Sample 2 | 448.4 | 6.60 | 1.46 |
| Sample 3 | 449.2 | 5.90 | 1.32 |

**Method Comparison**

A comparison of the High-Q ALP - ML (y) with a commercial obtainable assay (x) gave following results with 80 samples.

$y = 0.992 x + 2.64$; $r = 0.991$

**Notes :**

1. Avoid contact with skin and mucous membranes. The reagents contain sodium azide as preservative. Do not swallow.
2. During the reaction p-nitrophenol is produced. This substance is poisonous when inhaled, swallowed or when absorbed through the skin. If the reaction mixture comes into contact with skin or membrances, wash copiously with water and consult a doctor.

**References**


1. Bablok W et al. A General Regression Procedure for Method Transformation. J Clin Chem Clin Biochem 1988;26:783-790.
2. Bessey OAH et al. J Biol Chem 1946;164:321
3. Empfehlungen der Deutschen Gesellschaft für Klinische Chemie. Standard-Methode zur Bestimmung der Aktivität der alkalischen Phosphatase. Z klin Chem u klin Biochem 1972;10:191.
4. Glick MR, Ryder KW, Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation. Clin Chem 1986;32:470-474.


**Ordering information**

| Ref./Cat. | Pack Size | Presentation |
|---|---|---|
| P-ALP(ML) - 50 | 5 x 10 ml | Single Liquid Reagent |
| P-ALP(ML) - 100 | 4 x 25 ml | |
| P-ALP(ML) - 200 | 8 x 25 ml | |

## Product Features

- **Liquid Stable, Ready to use Mono Reagent**
- **PNPP Analogue used for better stability**
- **110 Seconds increasing kinetic reaction (20 Sec Delay+ 90 Sec Measuring)**
- **Measuring Wavelength 405 nm**
- **Kinetic factor 5500 at 37° C.**
- **Linearity 1250 IU/L**
- **Serum is the only specimen**
- **Available as multipurpose reagents and dedicated system packs**

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Symbols used with IVD devices

| | | | |
|---|---|---|---|
| | Date of manufacture | | Manufactured by |
| IVD | In vitro diagnostic device | | Keep away from sunlight |
| | Do not freeze | | This way up |
| | Use by (yyyy-mm-dd or mm/yyyy) | R | Reagent |
| CAL | Calibrator Material | LOT | Batch code |
| 2°C 8°C | Temperature limitation (store at) | CONTROL | Control |
| | Consult instructions for use | | Keep dry<br>Keep away from rain |
| REF | Catalog Number | | |

eIFU Indicator

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