ACCUCARE®

# ALKALINE PHOSPHATASE MONO

Kinetic UV Test – Optimized IFCC method

**Quantitative determination of Alkaline Phosphatase in serum / plasma.**
**Only for *In Vitro* Diagnostic use**

## ORDER INFORMATION

| REF | Pack Size |
|---|---|
| ALPM 50 | 50 X 1 ML |

## CLINICAL SIGNIFICANCE

Alkaline phosphatase is a hydrolytic enzyme found in serum in numerous distinct forms which originate mainly from bone and liver. Physiological increases are found during bone growth in childhood and in pregnancy, while pathological increases are largely associated with hepatobiliary and bone diseases. Elevated activities are also observed in infectious hepatitis, bone disease, osteornalacia (rickets), bone metastases and hyperparathyroidism.

## METHOD

Kinetic photometric test, according to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).

## PRINCIPLE

Alkaline phosphatase (ALP) catalyses the hydrolysis of p-nitrophenyl phosphate at alkaline pH, liberating p-nitrophenol and phosphate, The rate of p-Nitrophenol formation, measured photometrically, is proportional to the catalytic concentration of alkaline phosphatase present in the sample.

## REAGENT

Reagent I : ALP Substrate Reagent in MONO vials

## REAGENT PREPARATION

The reagent supplied is ready to use.

## REAGENT STORAGE AND STABILITY

1. The reagent is stable till the expiry when stored properly at 2 - 8°C and protected from direct sunlight.

## WARNING AND PRECAUTIONS

- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

## WASTE MANAGEMENT

Please refer to local legal requirements.

## MATERIALS REQUIRED BUT NOT PROVIDED

- NaCl solution 9 g/L
- General laboratory equipment

## SAMPLE COLLECTION AND PRESERVATION

**Serum:** Use non - haemolysed serum.

**Plasma:** Use heparin. Do not use EDTA, Oxalate or Fluoride.

Do not use hemolytic samples!

Stability:
7 days at 4 – 8 °C
2 months at –20 °C in case of immediate freezing.
Freeze only once! Discard contaminated specimens!

## ASSAY PROCEDURE

### Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28°C, prior to analysis.

| Automated Parameters | |
|---|---|
| Wavelength | 405 nm |
| Cuvette | 1 cm light path |
| Reaction Temperature | 37°C |
| Measurement | Against distilled water |
| Reaction Type | Kinetic test |
| Reaction Direction | Increasing |
| Sample Volume | 20 µl |
| Reagent Volume | 1000 µl |
| Delay/Lag/time | 60 Secs |
| Interval time | 30 Secs |
| No. of Readings | 04 |
| Blank Absorbance limit | < 0.85 |
| Factor | 2720 |
| Low Normal at 37°C | 25 IU/L |
| High Normal at 37°C | 147 IU/L |
| Linearity at 37°C | 2000 IU/L |

## MANUAL ASSAY PROCEDURE

**Pipette into Test Tubes**

| | |
|---|---|
| Sample | 20 µl |
| Reagent | 1000 µl |

Mix well and Incubate at 37°C for 60 secs. Measure absorbance, increase every 30 sec for 2 minutes and determine the Δ A/min.

### SAMPLE DILUTIONS

- The method is linear to a concentration of 2000 IU/L.
- If the concentration exceeds this value, the sample should be diluted 1:1 with 0.9% saline solution and reassayed. Multiply the result by 2.

## CALCULATION

A/min. x 2720 = U/l Alkaline Phosphatase

## CALIBRATORS AND CONTROLS

For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

This method is traceable to the molar extinction coefficient.
It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

## PERFORMANCE CHARACTERISTICS

### WITHIN RUN

| Sample | Mean Concentration | SD | CV % |
|---|---|---|---|
| Level 1 | 72.41 | 2.58 | 3.57% |
| Level 2 | 204.13 | 4.19 | 2.05% |

### RUN TO RUN

| Sample | Mean Concentration | SD | CV % |
|---|---|---|---|
| Level 1 | 72.56 | 2.19 | 3.02% |
| Level 2 | 205.56 | 3.91 | 1.91% |

## LINEARITY

The method is linear to a concentration of 2000 IU/L.
If the concentration exceeds this value, the sample should be diluted 1:1 with 0.9% saline solution and reassayed. Multiply the result by 2.

**Limit of detection**: The limit of detection for Alkaline Phosphatase is 2U/L.

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## METHOD COMPARISON

A comparison of Accucare Alkaline Phosphatase Mono with a commercially available assay (x) using 59 samples gave following results: $R^2 = 0.9900$

## REFERENCE VALUES

| | |
|---|---|
| ADULTS | 25-147 IU/L |
| Children | |
| Aged 1 day | < 250 IU/L |
| Aged 2-5 day | < 231 IU/L |
| Aged 6 day – 6 Months | < 449 IU/L |
| Aged 7Months-1 Year | < 462 IU/L |
| Aged 1-3 Year | < 281 IU/L |
| Aged 4-6 Year | < 269 IU/L |
| Aged 7-12 Year | < 300 IU/L |
| Aged 13-17 Year | < 390 IU/L |

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

## LIMITATION OF THE PROCEDURE

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

## INTERFERENCE

- Bilirubin: No interference found upto Bilirubin 40mg/dl.
- Hemoglobin: No interference found upto Hemoglobin 400mg/dl.
- Lipemia: No interference found upto 900mg/dl.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

## BIBLIOGRAPHY

1. Zilva JF, Pannall PR, "Plasma Enzymes in Diagnosis" in Clinical Chemistry in Diagnosis and Treatment. Lloyd London 1979:Chap 15 343.
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3. Young DS. Effects of Drugs on Clinical Laboratory Tests. Third Edition 1990: 3: 19-25.
4. Tietz Textbook of Clinical Chemistry and Molecular Diagnosis (4th Ed.) Burtis, Ashwood & Bruns (Eds), Elsevier Saunders, 2005; 2290.

## GLOSSARY OF SYMBOL

| | | | |
|---|---|---|---|
| | Consult Instruction for Use | LOT | Lot Number |
| REF | Catalog Number | | Date of Manufacturing |
| | Store between | | Use By or Expiration Date |
| | Manufacturer | IVD | For *in vitro* Diagnostic use only |
| | Keep away from sunlight | CONT | Content of the kit |

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