INTRODUCTION

1. AutoZyme Acid Phosphatase is a reagent set for determination of Acid Phosphatase activity **based on kinetic method** using α-naphthylphosphate.
2. AutoZyme Acid Phosphatase is **a single reagent system** using one step procedure.
3. AutoZyme Acid phosphatase can be determined in just **8 minutes** at 37°C.
4. AutoZyme Acid Phosphatase is **linear** upto 75 IU/l.
5. AutoZyme Acid Phosphatase can be used on any **Spectrophotometer, Discrete semiautomated and Automated analyzer.** Programme can be designed for any specific analyzer upon request.

PRINCIPLE

In acidic pH of buffer system, Acid Phosphatase hydrolyses α-naphthylphosphate to α-naphthol and phosphate. The α-naphthol is then coupled with Diazotized Fast Red TR to form a Diazo dye which has strong absorbance at 405 nm. The increase in absorbance is directly proportional to the level of acid phosphatase in serum.

The addition of L-Tartrate inhibits prostatic acid phosphatase but does not inhibit other isoenzyme.

The activity of Prostatic Acid Phosphatase is obtained by subtracting the result of Non prostatic Acid phosphatase (Determination with Tartrate) from Total Acid Phosphatase (without tartrate).

α-naphthylphosphate + H_2O $\xrightarrow{\text{Acid Phosphatase}}$ α-naphthol + Phosphate

α-naphthol + Fast Red TR ⟶ Diazonium Dye

PREPARATION OF WORKING SOLUTION

Total Acid Phosphatase Working Solution

Dissolve the contents of the substrate bottle with Diluent for Total ACP as per instructions indicated on individual bottle label to prepare working solution.

Non Prostatic Phosphatase Working Solution

Dissolve the contents of the substrate bottle with Diluent for Non Prostatic ACP as per instructions indicated on individual bottle label to prepare working solution.

The Stabilizer reagent (Acetate Buffer) is ready-to-use as provided.

NOTE : ACP = Acid Phosphatase

REAGENT STORAGE & STABILITY

The kit should be stored at 2 - 8°C and is stable till the expiry date indicated on the label.

The working solutions of — Non Prostatic Acid Phosphatase & Total Acid Phosphatase are stable for **7 days** at 2 - 8°C.

COMPONENTS & CONCENTRATION OF WORKING SOLUTION

Component	Concentration	
	Total ACP	**Non Prostatic ACP**
• Buffer, pH 5.3	80 mmol/l	80 mmol/l
• α - naphthylphosphate	> 5.0 mmol/l	> 5.0 mmol/l
• Fast Red TR	> 1.0 mmol/l	> 1.0 mmol/l
• Tartrate	—	150 mmol/l

SPECIMEN COLLECTION & PRESERVATION

Serum sample must be completely free from haemolysis. Acid Phosphatase is very unstable at the pH of serum. **Immediately after separation of the serum from the clot, stabilize the serum by the addition of 20 µl of stabilizer reagent (Acetate buffer) to every 1 ml of serum.** The enzyme activity will be stable for 3 days at 2-8°C. Oxalate & fluoride as anticoagulants will interfere with the assay

PROCEDURE

- ☐ **Reaction type ..... Kinetic**
- ☐ **Reaction direction ..... Increasing**
- ☐ **Wavelength ..... 405 nm.**
- ☐ **Flowcell temperature ..... 37°C**
- ☐ **Zero setting with ..... Distilled water**
- ☐ **Delay time ..... 300 seconds**
- ☐ **No. of readings 4**
- ☐ **Interval ..... 60 seconds**
- ☐ **Blank absorbance limit ..... < 0.500**
- ☐ **Sample volume ..... 0.1 ml (100 µl)**
- ☐ **Reagent volume ..... 1.0 ml**
- ☐ **Factor 743**
- ☐ **Linearity ..... 75 IU/l**

Manual assay procedure

Prewarm at 37°C the required amount of working solutions before use.

Perform the assay as given below :

Total Acid Phosphatase

Specimen	**0.1 ml (100 µl)**
Total ACP working solution	**1.0 ml**

Non Prostatic Acid Phosphatase

Specimen	**0.1 ml (100 µl)**
Non Prostatic ACP working solution	**1.0 ml**

For each assay, mix thoroughly and transfer the assay mixture immediately to the thermostated cuvette and start the stop watch simultaneously. Record the first reading at 300th second and subsequently three more readings with 60 seconds interval at 405 nm.

Calculation:

A) Total Acid Phosphatase & Non Prostatic Acid Phosphatase

Conc. in IU/l = 743 x Δ Abs. / min

B) Prostatic Acid Phosphatase

Conc. in IU/l =Total Acid Phosphatase - Non Prostatic Acid Phosphatase

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EXPECTED VALUES

Total Acid Phosphatase : upto 4.7 IU/l

Prostatic Acid Phosphatase : upto 1.6 IU/l

NOTE :

Since the expected values are affected by age, sex, diet and geographical location, each laboratory is strongly urged to establish its own reference range for this procedure.

PROCEDURE LIMITATIONS

1. Working reagent is considered unsatisfactory and should not be used if its absorbance exceeds 0.500 at 405 nm. against distilled water.
2. If the Acid Phosphatase activity is above 75 IU/l then dilute the specimen suitably with normal saline. In such case the results obtained should be multiplied by dilution factor to obtain correct Acid Phosphatase activity.

QUALITY CONTROL

To ensure adequate quality control, it is recommended that each batch should include a normal and an abnormal commercial reference control serum. It should be realised that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glassware and accuracy of pipetting.

Liquid dispensing facility

IVD	*In Vitro* Diagnostic Use		Date of Manufacturing
	Consult Instructions for use		Use by (YYYY-MM-DD)
REF	Catalogue Number		Temperature Limitation
LOT	Batch Code		Manufacturer

CE European Conformity

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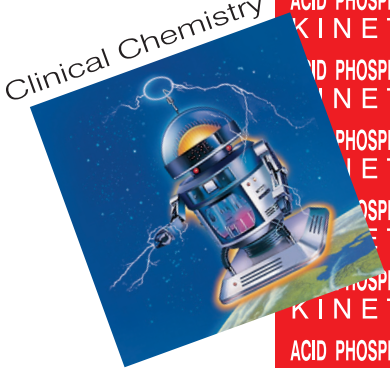
ACCUREX BIOMEDICAL PVT. LTD.



AutoZyme

ACID PHOSPHATASE

Kinetic

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