BIOSS
See Life More Clearly

5 x 2 mL
51201001

ACID PHOSPHATASE

Intended Use
This reagent is intended for *in vitro* quantitative determination of Acid phosphatase in serum.
- Alpha - naphthylphosphate method.
- Linear upto 150 U/L.
- Tartrate included for determination of non-prostatic acid phosphatase.

Clinical Significance
Acid phosphatase is present in lysosomes, which are organells present in all cells with the possible exception of erythrocytes. The greatest concentrations of ACP activity occurs in liver, spleen, erythrocytes, platelets, bone marrow & the prostate gland which is the richest source and it contributes a small portion of the enzyme present in sera from healthy males.

Determination of ACP activity in serum is almost directed toward the prostatic enzyme with the intent of detecting or monitoring carcinoma of the prostate. Elevation of the enzymatic activity of prostatic ACP & thus of total ACP activity are found in the sera of about 60% of men with prostatic cancer & metastase.

Slight or moderate elevations in total ACP activity often occur in Pagets disease in hyperparathyroidism with skeletal involvement & in the presence of malignant invasion of the bones by cancers, such as breast cancer in women, unlike prostatic ACP, in these cases the serum ACP activity is not inhibited by tartrate.

Principle
Acid Phosphatase activity present in the sample is determined according to the following reactions.

$$\text{alpha-naphthyl-phosphate} + H_2O \xrightarrow{\text{Acid Phosphatase}} \text{alpha -naphthol} + \text{phosphate}$$

$$\text{a-naphthol} + \text{Fast Red TR} \longrightarrow \text{Azo dye}$$

Tartrate is used as specific inhibitor of the prostatic fraction.

Kit Components

Reagent/ Component	Product Code 51201001	Description	
Acid phosphatase R1	5 x 2 mL	Citrate Buffer (pH 5.2)	50 mmol/L
Acid phosphatase R2 (Tablets)	1 x 5 x 2 mL	alpha-naphtylphosphate Fast red TR	10 mmol/L 6 mmol / L
Acid phosphatase R3	1 x 1 mL	Sodium tartrate	2 mmol/L

Risk & Safety
Material Safety data sheets (MSDS) will be provided on request

Reagent Preparation
Dissolve one tablet (R2) with 2 mL of Reagent 1 (R1)
The working reagent is stable for 2 days at 2-8°C.
Wait for 10 minutes for complete dissolution.

Reagent Storage and Stability
The sealed reagents are stable upto the expiry date stated on the label, when stored at 2 - 8°C.

Reagent Deterioration
Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

Precaution
To avoid contamination, use clean laboratory wares. Use clean, dry disposable pipette tips for dispensing. Close reagent bottles immediately after use.

Avoid direct exposure of reagent to light.Do not blow into the reagent bottles.

This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents.

Acid phosphatase is extremely temperature labile. The sample should therefore be centrifuged immediately after coagulation. The serum should be cooled and proceed as quickly as possible. Do not use hemolytic serum. If the serum is to be examined after some time, its pH value should be adjusted to about 5 (0.02 mL acetate buffer 5 M per 1 mL of serum).

Waste Management
Reagents must be disposed off in accordance with local regulations.

Sample
Fresh serum only. Do not use plasma.

Materials provided
Acid Phosphatase R1, Acid Phosphatase R2 & Acid Phosphatase R3

Materials Required but Not Provided
- Pipettes & Tips
- Test Tubes & racks
- Timer
- Incubator
- Analyzer

Test Parameter

Mode of Reaction	Kinetic
Slope of Reaction	Increasing
Wavelength	405 nm
Temperature	37 °C
Factor	750
Blank	DI Water
Linearity	150 U/L
Delay Time	300 sec
No of reading	3
Interval	60 sec
Sample Volume	100 µL
Reagent Volume	1000 µL
Cuvette	1 cm light path

Calibration
Use provided factor (750) for estimation of Acid Phosphatase.

Procedure Notes

Laboratory Procedure for Semi Auto Analyzer		
	Total	Non Inhibitor by tartrate fraction
Working Reagent	1000 µL	1000 µL
Tartrate Solution R3	-	10 µL
Sample	100 µL	100 µL
Mix, and incubate for 5 minutes at 37°C. Measure the change in absorbance per minute (△ OD/min) during 3 minutes.		

Calculation
Total acid phosphatase (U/L) = 750 x (△ OD/min.) of total
Non prostatic ACP activity (U/L) = 750 x (△ OD/min.) of non inhibitor fraction.
Fraction of prostatic acid phosphatase(U/L) = Total ACP activity - Non-prostatic ACP activity.

Quality Control
It is recommended to use control to verify the performance of the assay. Each laboratory has to establish its own internal quality control scheme and procedure for corrective action, if control do not recover within the acceptable range.

SYMBOLS USED ON THE LABELS: IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

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ADS/V.02/060114

CE ISO 9001 : 2008
ISO 13485 : 2003

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Reference Range

It is recommended that each laboratory has to establish its own reference values.
The following value may be used as guide line.
Total acid phosphatase:

Men	: < 5.4 U/L
Women	: < 4.2 U/L
Prostatic acid Phosphatase	: < 1.7 U/L

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance

1. Linearity

This reagent is linear upto 150 U/L.
If the concentration is greater than linearity (150 U/L) dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

2. Precision

Accuracy (U/L)

Control	Expected Value	Measured Value
Control Level 1	8.78 ± 2.90	8.91
Control Level 2	20.8 ± 6.9	20.37

3. Sensitivity

Lower detection limit is 1 U/L

Bibliography

Hillman G. Z., Clin.Chem. Biochem 9.273 (1971)

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