ACCUCARE®

ACID PHOSPHATASE

Kinetic color method

Quantitative determination of Acid Phosphatase in serum.
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Pack Size
ACP 10	10 X 1.1 ML

CLINICAL SIGNIFICANCE

High ACP activity is observed in cases of prostatic cancer, slight or moderate ACP activity is found in Paget's disease, in hyperparathyroidism and in the presence of malignant invasion of the bones by cancer, such as breast cancer in women.

Method

Kinetic photometric test.

PRINCIPLE

In acid environment α-naphthyl phosphate is hydrolysed by acid phosphatase to produce alpha-napthol and phosphate. Alpha-napthol reacts with diazo-2-chloro-5-toluene (FAST RED TR) forming an azo dye compound which absorbs maximally at 405 nm and is directly proportional to total acid phosphatase activity. When the activity is measured in the presence of tartrate the prostatic activity is inhibited. The difference between Total and Nonprostatic acid phosphatase corresponds to prostatic fraction.

REAGENT

Reagent I : Buffer reagent
Reagent II : Substrate reagent
Reagent III : Tartrate reagent
Reagent IV : Acetate buffer

REAGENT PREPARATION

TOTAL ACID PHOSPHATASE

Dissolve the contents of one vial of substrate with the volume of buffer as specified on the vial & label it as A.

NON PROSTATIC ACID PHOSPHATASE

Dissolve the contents of one vial of substrate with the volume of buffer as specified on the vial and label it as B then add 10 µl of sodium tartrate in 1 ml of reconstituted reagent.

REAGENT STORAGE AND STABILITY

1. All reagents should be stored refrigerated (2-8°C) and can be used until the expiration date indicated on the label.

Reconstituted Reagent A & B is stable for 5 days refrigerated (2-8°C), when stored in an amber vial protected from direct light.

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 only.
Storage: ACP, especially the prostatic fraction, is unstable in a collected sample hence the serum should be separated from the clot, as soon as possible, and assayed. In case of a delay in testing the serum should be acidified to a pH of 5.0 with 0.02 ml Acetate Buffer (5M) provided for each ml of serum. The enzyme activity will be stable for three days at 2-8°C.

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 - 28ºC, prior to analysis.

Automated Parameters	
Wavelength	405 nm
Cuvette	1 cm light path
Reaction Temperature	37°c
Measurement	Against Distilled water
Reaction	Kinetic
Reaction Direction	Increasing
Sample Volume	100 µl
Reagent Volume	1000 µl
Delay	300 sec
Interval	60 sec
No of readings	4
Blank Absorbance Limit	< 0.800
Linearity	75 IU/L

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

Sample	100 µl
Working Reagent	1000 µl

Mix well, and after 5 mins at 37°C Measure the increase in absorbance of the Sample every minute for 4 minutes. Calculate the mean absorbance change per minute (ΔA/Min)

SAMPLE DILUTIONS

- If the Acid Phosphatase concentration exceeds the reagents reportable dynamic range (Linearity) of 75 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

Total ACP	= ΔA / min x 743
Non Prostatic ACP	= ΔA / min x 743

Prostatic ACP concentration = Total ACP - Non Prostatic ACP

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.

Art No.: IFU/BC/ACP
Effective Date: 20/09/2019
Revision No.: 01

PERFORMANCE CHARACTERISTICS
WITHIN RUN

Sample	Mean Concentration	SD	CV %
Norm Control	22.75	0.78	3.44
Path Control	39.87	1.27	3.19

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Norm Control	22.67	0.62	2.7%
Path Control	40.21	1.13	2.8%

LINEARITY
The method is linear to a concentration of 75 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 Acid Phosphatase is 0.7 IU/L.

METHOD COMPARISON
A comparison of Accucare Acid Phosphatase with a commercially available assay (x) using 59 samples gave following results: R^2 = 0.9600

REFERENCE VALUES

Total Acid Phosphatase	2.5 -11.7U/L
Prostatic Acid Phosphatase	0.2 - 3.5 U/L

It is strongly recommended laboratory establish its own normal range

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 3.2 mg/dl.
- Hemoglobin: No interference found upto 62 mg/dL.
- Lipemia: No interference found upto 250 mg/dL.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY
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2. Hillman, G.Z., Klin Chem., Klin. Biochem, 3, 273, 1971.
3. Doe, R.P., Mellinger, G.T., and Seal U.S. Clin. Chem. 11, 943, 1965.
4. Young DS. Effects of Drugs on Clinical Laboratory Tests Third Edition 1990; 3: 4-5.
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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

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No.: 3225, Chemical Zone,
GIDC Sarigam – 396155, Dist. Valsad, Gujarat, India.
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