

Ana-Chek® ACID PHOSPHATASE

METHOD – α -NAPHTHYLPHOSPHATE

PRODUCT CODE – LA01



INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of ACP activity in serum/plasma using α -Naphthylphosphate Kinetic method.

SUMMARY AND PRINCIPLE

Increased activities of total and prostate specific acid phosphatase are associated with prostate gland disorders (cancer). Elevations in total enzyme activity are observed also in cases of myeloma, thrombocytopenia and some liver diseases. Ana-Chek® Acid Phosphatase is a reagent set for quantitative determination of Acid phosphatase activity based on kinetic method using naphthylphosphate. Ana-Chek® Acid Phosphatase is a single reagent system using one step reconstitution.



KIT COMPONENTS

Reagent 1	: ACP Substrate
Reagent 2	: TAP Diluent
Reagent 3	: NAP Diluent
Reagent 4	: Stabilizer

REAGENT PREPARATION, STORAGE & STABILITY

- Total Acid Phosphatase working reagent:** Dissolve the contents of the substrate bottle for Total ACP with diluent for Total ACP to prepare working reagent.
- Non-prostatic Acid Phosphatase working reagent:** Dissolve the contents of the substrate bottle for non-prostatic ACP with diluent for non-prostatic ACP to prepare working reagent.
- The working reagent of Non prostatic Acid Phosphatase and Total Acid Phosphatase are stable for 7 days at 2-8 °C.
- The Stabilizer reagent (Acetate buffer) is ready to use as provided. The kit should be stored at 2-8 °C and is stable till the expiry date indicated on the label.

PRECAUTIONS & HANDLING

The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent. Do not shake the reagent vigorously. Discard the reagent if the absorbance of the reagent exceeds 0.500 O.D. against D/W at 405 nm. Contamination of the reagent should be avoided.

TEST PARAMETERS

Name	Acid Phos	Reagent Volume	1000 μ l
Reaction Type	Kinetic ($\uparrow$)	Sample Volume	100 μ l
Wavelength Primary	405 nm	Incubation Temp.	37 °C
Flow Cell Temp.	37 °C	Delay Time	300 sec.
Blank setting	D.W.	Read Time	60 sec.
Blank Abs Limit	<0.500	Factor	743
Linearity	75 IU/L	Standard Conc.	-

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls, Incubation chamber.

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Serum must be free from haemolysis. Oxalate and fluoride as anticoagulants interfere with assay. ACP is unstable at the pH of serum. Add 20 μ l of stabilizer per ml serum after separation. Acid Phosphatase is stable for 3 days at 2-8 °C.

COMPONENTS OF REAGENT

Component	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		> 1.0 mmol/l
Stabilizers and inactive ingredients.		

ASSAY PROCEDURE

	Test
Reagent	1000 μ l
Serum / Plasma	100 μ l
Mix the reagent and sample in the above-mentioned ratio	
Aspirate the reaction mixture into the flow cell and record the absorbance at 5 th , 6 th , 7 th and 8 th minutes.	

CALCULATION

Total ACP / Non-Prostatic ACP Activity (IU/L) = Avg. Abs/min x 743.
Prostatic ACP = Total ACP – Non-Prostatic ACP.

REFERENCE VALUES FOR NORMAL PEOPLE

Total Acid Phosphatase : upto 4.7 IU/L.
Prostatic Acid Phosphatase : upto 1.6 IU/L.

PERFORMANCE CHARACTERISTICS

Measuring Range: The assay is linear between 4 - 75 IU/L. If the Acid Phosphatase value exceeds linearity limit (above 75 IU/L), dilute the specimen suitably with normal saline and repeat the assay. In that case, assay value should be multiplied with the dilution factor to obtain correct Acid Phosphatase value of the specimen.

Interference: There is no significant interference in samples containing Bilirubin upto 20 mg/dL, Ascorbic Acid upto 8 mg/dL and Haemoglobin upto 500 mg/dL.

Precision: Precision studies has been carried out using quality control sera as shown below:

Acid Phosphatase - TAP

(n=10)	Within Run			Between Run		
Specimen Material	Mean (IU/L)	SD (IU/L)	CV %	Mean (IU/L)	SD (IU/L)	CV %
Low Value Serum	21.56	0.97	4.5	23.59	1.00	4.2
High Value Serum	44.70	0.65	1.4	54.8	0.062	1.1

Acid Phosphatase - NAP

(n=10)	Within Run			Between Run		
Specimen Material	Mean (IU/L)	SD (IU/L)	CV %	Mean (IU/L)	SD (IU/L)	CV %
Low Value Serum	12.55	0.51	4.0	12.89	0.57	4.4
High Value Serum	30.88	0.96	3.1	27.74	1.32	4.8

Note: We recommend all the laboratories to establish its own accuracy and precision data.

QUALITY CONTROL

Inclusion of a normal value and abnormal value chemistry control serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides between run precision and accuracy data for Acid Phosphatase. We recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

PRECAUTIONS

1. Discard the working reagent if its absorbance is less than 0.500 at 405 nm against distilled water.
2. Haemolysis must be avoided.
3. If the Acid Phosphatase activity exceeds 75 IU/L then dilute the specimen suitably with normal saline and repeat the assay. In such case multiply the result obtained with the dilution factor to obtain correct Acid Phosphatase activity.

BIBLIOGRAPHY

1. Hillman G.-Z.Klin.Chem. klin Biochem.9 (1971); 273 22 - 24.
2. Seiler.D., Nagel, Tritschler W. and Looser,s J.Clin.chem.Clin Biochem 21 (1983); 519.

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

ANAMOL LABORATORIES PVT. LTD.
61, Genesis Industrial Township, Kolgaon,
Palghar – 401 404. India.
Customer Care & WhatsApp: +91-9823388695.

admin@anamollabs.com
exports@anamollabs.com
www.anamollabs.com

ISO 9001: 2015
ISO 13485: 2016
GMP
CE