Acid PHOSPHATASE

Kinetic colorimetric method

10 x 3 ml **REF CP02-30**

Intended use

Kit for quantitative determination of Total and Prostatic Acid Phosphatase ACP (EC 3.1.3.2.) on serum.

Principle

In acid medium, acid phosphatase (ACP) catalyzes α-naphtylphosphate (α-NP) hydrolysis into α-naphtol and phosphate. α-naphthol reacts with diazo 2-chloro-5-toluene (fast red TR salt) and forms an azo-dye compound. The formation rate of the azo compound at 405 nm is proportional to total acid phosphatase activity. Prostatic origin acid phosphatase is inhibited by tartrate and is detected as the difference between total acid phosphatase and non-prostatic acid phosphatase.

Sample

Serum. Avoid hemolyzed samples.
The sample can be stabilized by adding 30 µl, of Reagent 3 to 1 ml of serum.
STABILITY: 3 days at 2-8°C.

Kit Components

Reagents	REF CP02-30	Quantity	Risk
REAGENT 1A	CP02-30R1	10 vials (powder)	*
REAGENT 1B	CP02-30R2	1 x 35 ml	
REAGENT 2	CP02-30R3	1 vial (powder)	
REAGENT 3	CP02-30R4	1 x 1 ml	*
SPOON		1	

Reagents

REAGENT 1A α-naphtylphosphate 0,036 mmol/L, fast red TR 0,002 mmol/L, excipient
REAGENT 1B Citrate buffer (pH 5,0) 150 mmol/L, 1-5-pentandiol 200 mmol/L
REAGENT 2 Sodium tartarate 1 g
REAGENT 3 Acetic acid 0,9 mol/l

Stability: store at 2-8°C and protect from light to keep the reagents stable up to the expiration date on the label. Do not freeze. Keep bottles closed when not in use.

Total ACP
Preparation of working reagent

Mix 1 vial of Reagent 1A with exactly 3 ml of Reagent 1B.
Shake gently until complete dissolution of the powder.
Wait 5 -10 minutes before use.
STABILITY: 1 day at 20-25°C, 5 days at 2-8°C in a closed bottle away from the light.

Non-Prostatic ACP
Preparation of working reagent

Mix 1 vial of Reagent 1A with 3 ml of Reagent 1B. Add 3 spoons of Reagent 2. Shake gently until the complete dissolution of the powder. Wait 5-10 minute before use.
STABILITY: 1 day at 20-25°C, 5 days at 2-8°C in a closed bottle away from the light.

Manual Assay Procedure

Analysis:	increasing kinetic
Wavelength:	405
Cuvette:	1 cm optical path
Temperature:	30, 37°C
Reaction Time:	3 minutes
Reading:	against air or distilled water
Sample/Reagent:	1/10

Let the working reagent reach the chosen temperature for the analysis.

Pipette in cuvette:

	Total ACP	Non Prostatic ACP
Sample	100 µl	100 µl
Working reagent (Total ACP)	1,0 ml	---
Working reagent (Non prostatic ACP)	---	1,0 ml

Mix and pour into the test cuvette. Incubate at the test temperature for 5 minutes. Read initial absorbance and repeat reading at constant intervals of 1 minute, for 3 minutes. Calculate the average value of the absorbance variations per minute (ΔA/min).

Reaction volumes can be proportionally varied without any change in calculation.

Calculation

Calculate Total ACP (U/L), Non-Prostatic ACP (U/L) and Prostatic ACP enzymatic activities in the sample using the following formulas:

Total ACP [U/L] and Non-Prostatic ACP [U/L] = ΔA/min x 750

Prostatic ACP [U/L] = Total ACP [U/L] – Non-Prostatic ACP [U/L]

Reference values

Total ACP

	30°C	37°C
Men	up to 4,2 U/L	up to 4,7 U/L
Women	up to 3,0 U/L	up to 3,7 U/L

Prostatic ACP

	30°C	37°C
	up to 1,5 U/L	up to 1,6 U/L

Each laboratory should define its own reference values for this method.

Quality control

A quality control program is recommended for all clinical laboratories. Control sera in normal and high ranges for each assay are recommended.
The obtained values should be included within the manufacturer's accepted ranges for the method used.

Performance characteristics

Sensitivity: the sensitivity of the method is 1 U/L.

Linearity: up to 150 U/L (at 37°C).
For higher values, dilute the samples 1:10 with saline solution and multiply the result by 10.

Within-run precision:

	Level 1	Level 2
Average [U/L]	4,8	24,3
DS	0,25	1,11
CV %	5,2	4,6

Between-run precision:

	Level 1	Level 2
Average [U/L]	4,6	25,2
DS	0,31	1,36
CV %	6,7	5,4

Interferences: up to 30 mg/dl of bilirubin does not interfere.

Notes

- (*) dangerous reagents are marked by an asterisk. Refer to safety data sheet
- wear proper protective clothes - do not pipette by mouth
- disposal of reagents and waste according to local laws
- read the kit instructions before performing the test
- use only the reagents in the kit and recommended reagents
- chemistry analyzer parameters are available.

Warnings and precautions

WARNING

REAGENT 1 A ***H315*** It can cause skin irritation. ***H319*** Causes severe eye irritation. In case of contact with the eyes: rinse thoroughly for several minutes. If the irritation continues, see a doctor. ***H335*** May cause respiratory irritation.

REAGENT 3: **H314** Causes severe skin burns and eye damage.

References

1. Hillmann G.- Z.Klin. Chem.Klin. Biochem. 1971, 9, 273-274.
2. Kaplan LA, Pesce AJ: "Clinical Chemistry", Mosby Ed. 1989

IVD CE

Ed. 01- Mar 2021 RR

Manufacturer

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Keys symbols

IVD	In Vitro diagnostic medical device
LOT	batch number
REF	catalogue number
	temperature limits
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	caution
	read instructions for use

Ed. 01 - 11/2021 RR