DIAGNOSTIC KIT FOR DETERMINATION OF TOTAL, NON PROSTATIC AND PROSTATIC ACID PHOSPHATASE ACTIVITY

OS – ACP

INTRODUCTION

Acid phosphatases (ACP) are a group of enzymes that can be found in liver, spleen, erythrocytes, platelets, bone marrow and prostate gland. The ratio between total acid phosphatase and prostatic phosphatase is healthy males is about 1:1. Activity of total acid phosphatase increases in case of Paget's disease, hyperparathyroidism, bone cancer, Gaucher'a disease, Niemann-Pick disease and myelocytic leukaemia. Prostatic acid phosphatase levels increase in case of prostatic cancer.

METHOD PRINCIPLE

Acid phosphatases catalyses the hydrolysis, in acid medium, of 1-naphtylphosphate (1-NP) into 1-naphtol and phosphate. 1-naphtol reacts with diazo-2-chloro-5-toluene (Fast Red TR salt), forming an azo dye compound with absorbance increase is proportional to the total acid phosphatase activity (ACP). Prostatic acid phosphatase (ACP-P) is inhibited by tartrate and is detected with an indirect method by subtraction between ACP and non-prostatic acid phosphatase (ACP-NP).

REAGENTS

Package REAGENT 1a REAGENT 1b TARTRATE REAGENT ACETIC ACID SOLUTION

6 x 20 ml 6 vials (powder) 1 vial (powder) 1 x 3 ml

(acetic acid 0.1 mol/l) small spoon 1 1

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents must be limpid; do not use if turbid. Protect from light and avoid contamination!

Working reagents stability

Stability of working reagents ACP and ACP-NP after reconstitution: 7 days at 2-8°C, if contamination avoided and bottle recapped immediately after use.

Concentrations in the working reagent ACP

 citrate buffer (pH 5.4)
 0.1 mol/1

 1-NP
 10 mmol/1

 Fast Red TR salt
 > 1.0 mmol/1

 Concentrations in the working reagent ACP-NP

 citrate buffer (pH 5.4)
 0.1 mol/l

 1-NP
 10 mmol/l

 Fast Red TR salt
 > 1.0 mmol/l

 sodium tartrate
 0.18 mol/l

Warnings and notes

- Product for in vitro diagnostic use only.
- It is recommended to carry out the prostatic acid phosphatase test only on samples with total acid phosphatase activity > 3.5 U/l as it is possible to obtain not reliable with a total acid phosphatase activity lower than the above-mentioned limit.
- Controls and calibrators used in determination of ACP should be used according to the guidelines contained in their instruction for use.
- A slight pink coloration of working reagents ACP and ACP-NP does not affect the reagents performance.
- reagents performance.
 ACETIC ACID SOLUTION meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008.

Ingredients:

ACETIC ACID SOLUTION contains acetic acid.

Danger



H314 Causes severe skin burns and eye damage.

H318 Causes eye damage.

P280: Wear protective gloves/protective clothing/eye protection/face protection

P302+P352: IF ON SKIN: Wash with plenty of water

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P321: Specific treatment is urgently needed (go to see a doctor with the Safety data sheet for this product).

P501: Dispose of the contents/containers in accordance with the current legislation on waste treatment.

SPECIMEN

Fresh serum. Do not use haemolized, lipemic and icteric samples. Since the sample activity decreases of about 50% within an hour at room temperature, acidify the specimen immediately after collection by adding 20ul

specimen immediately after collection by adding 20µl ACETIC ACID SOLUTION for each ml of fresh serum.

Stability of acidified sample: 5 days at 2-8°C.

Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

These reagents may be used in automatic analysers Olympus AU400/AU640. For reagent blank 0.9% NaCl is recommended.

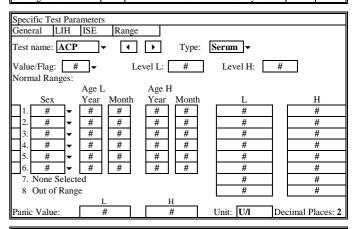
ACP ASSAY

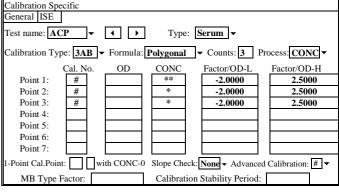
Working reagent ACP: Dissolve the contents of one bottle of Reagent 1b with the contents of one bottle of Reagent 1a. Let stand for about 10 minutes and gently mix. The contents pour into bottle of Reagent 1a, put in analyser and use application for ACP.



APPLICATION - ACP

Reagent ID: 001 Specific Test Parameters LIH ISE Range General **◆** Test name: ACP Type: Serum ▼ Operation: Yes Sample: Volume μL Dilution 0 μL Pre-Dilution Rate: 1 Reagents: R1 Volume 200 μL Dilution μL Min OD R2 Volume 0 μL Dilution 0 L **-2.0000** Reagent OD Limit: Pri. 410 Sec. 660 First L -2.0000 First H 2.5000 Wavelength: Last L -2.0000 Last H 2.5000 Method: RATE Dynamic Range Reaction Slope: Measuring Point 1: First 10 L Last Measuring Point 2: First Last Correlation Factor: A 1.000 В 0.000 Linearity: No-Lag-Time On-board Stability Period:





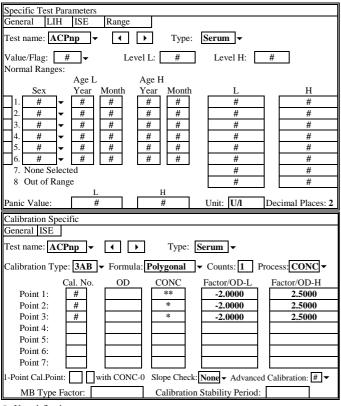
- # User defined
- * Calibrator value
- ** Saline should be used as calibrator 1

ACP-NP ASSAY

Working reagent ACP: Dissolve the contents of one bottle of Reagent 1b with the contents of one bottle of Reagent 1a. Let stand for about 10 minutes and gently mix. In order to determine ACP-NP activity add one small spoon contents (corresponding to 35-40 mg) of Tartrate Reagent for each 5 ml working reagent. Gently mix until complete solution. Such solution put in analyser and use application for ACP-NP.

APPLICATION – ACP-NP

Reagent ID: 008				
Specific Test Parameters				
General LIH ISE	Range			
Test name: ACPnp	• (Type: Se	rum ▼ Ope	ration: Yes 🕶
Sample: Volume	15 μL Ε	Dilution 0 μL	Pre-Dilution Rat	e: 1
Reagents: R1 Volume	200 μL E	Dilution 0 μL	Min OD	Max OD
R2 Volume	0 μL E	Dilution 0 μL	L -2.0000	Н 2.5000
			Reagent OD Lin	nit:
Wavelength: Pri.	410 ▼ S	Sec. 660 ▼	First L -2.0000	First H 2.5000
Method: R	ATE -		Last L -2.0000	Last H 2.5000
Reaction Slope:	+		Dynamic Range	:
Measuring Point 1: First	10 I	ast 25	L	Н
Measuring Point 2: First	I.	_ast	Correlation Fact	or:
Linearity:	15 %	· <u></u>	A 1.000	В 0.000
No-Lag-Time:	▼	On-board	Stability Period:	



- User defined
- Calibrator value
- ** Saline should be used as calibrator 1

CALCULATION OF ACP-P (prostatic acid phosphatase)

ACP-P[U/I] = ACP - ACP-NP

REFERENCE VALUES 4

ACP

serum	U/1	μkat/l
male	2.5 – 11.7	0.042 - 0.195
female	0.3 – 9.2	0.005 - 0.154

ACI-I		
serum (tartrate inhibition)	U/l	μkat/l
male	0.2 – 3.5	0.003 - 0.058
female	0.0 - 0.8	0.000 - 0.013

It is recommended for each laboratory to establish its own reference ranges for local population.

OUALITY CONTROL

For internal quality control of ACP it is recommended to use the CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) with each batch of samples. For internal quality control of ACP-NP it is recommended to use the control sera with each batch of samples.

systems the calibration of automatic analysers MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) and LEVEL 2 (Cat. No 5-175; 5-177) is recommended.

The calibration curve should be prepared with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using an automatic analyser. Results may vary if a different instrument is used.

- Sensitivity: ACP: 0.35 U/l (0.006 µkat/l). ACP-NP: 0.39 U/1 (0.007 µkat/l).
- Linearity ACP/ACP-NP: up to 75 U/l (1.25 µkat/l).

For higher activity than 75 U/l dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.

Specificity / Interferences

Haemoglobin up to 0.15 g/dl, triglycerides up to 400 mg/dl, bilirubin up to 20 mg/dl and do not interfere with the test.

Precision

ACI			
Repeatability (run to run)	Mean	SD	CV
n = 20	[U/l]	[U/1]	[%]
level 1	6.7	0.26	3.87
level 2	13.8	0.37	2.70
level 3	28.0	0.64	2.30

Reproducibility (day to day) n = 20	Mean [U/l]	SD [U/I]	CV [%]
level 1	6.64	0.27	4.06
level 2	13.84	0.37	2.64
level 3	28.10	0.62	2.22

ACP-NP

1101 111			
Repeatability (run to run)	Mean	SD	CV
n = 20	[U/l]	[U/l]	[%]
level 1	2.8	0.19	6.73
level 2	3.9	0.18	4.50
level 3	6.0	0.23	3.86

Reproducibility (day to day)	Mean	SD	CV
n = 20	[U/l]	[U/l]	[%]
level 1	2.93	0.17	5.88
level 2	3.90	0.19	4.95
level 3	5.96	0.23	3.82

Method comparison

A comparison between CORMAY reagent (y) and another commercially available assay (x) using 60 samples gave following results:

ACP

y = 1.0162 x + 0.10151 U/1;

(R – correlation coefficient) R = 0.997

y = 1.1325 x - 0.09887 U/l;

R = 0.998(R - correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

- NCCLS Document: "Procedures for the Collection of Arterial Blood specimens; Approved standard- Third Edition (1999)".
- Kaplan, L.A., Pesce A.J.,: "Clinical Chemistry", Mosby Ed. (1996)
- Jakobs, D.S., Kasten, Jr., B.L., Demmott, W.R., Wolfson, W.L.: "Laboratory Test Handbook", Lexi-Comp and Williams &Wilkins Ed. (2nd Edition-1990). Tietz N.W.: Textbook of Clinical Chemistry, 3rd ed., W. B. Saunders Company, 3
- Philadelphia, 1828 (1999).

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