Cat. No 9-454

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

READER 1a	6 x 20 ml
READER 1b	6 vials (powder)
TARTRATE REAGENT	1 vial (powder)
ACETIC ACID SOLUTION (acetic acid 0.1 mol/l)	1 x 3 ml
small spoon	1 pcs.

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/l
1-NP	10 mmol/l
Fast Red TR salt	> 1.0 mmol/l

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.
- 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 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
General | LIH | ISE | Range

Test name: **ACP** Type: **Serum** Operation: **Yes**

Sample: Volume	15	µL	Dilution	0	µL	Pre-Dilution Rate:	1		
Reagents: R1 Volume	200	µL	Dilution	0	µL	Min OD		Max OD	
R2 Volume	0	µL	Dilution	0	µL	L	-2.0000	H	2.5000
						Reagent OD Limit:			
Wavelength: Pri.	410		Sec.	660		First L	-2.0000	First H	2.5000
Method:	RATE					Last L	-2.0000	Last H	2.5000
Reaction Slope:	+					Dynamic Range:			
Measuring Point 1: First	10		Last	25		L		H	
Measuring Point 2: First			Last			Correlation Factor:			
Linearity:	15	%				A	1.000	B	0.000
No-Lag-Time:						On-board Stability Period:			

Specific Test Parameters
General | LIH | ISE | Range

Test name: **ACP** Type: **Serum**

Value/Flag: # Level L: # Level H: #

Normal Ranges:

	Sex	Age L Year	Age L Month	Age H Year	Age H Month	L	H
1.	#	#	#	#	#	#	#
2.	#	#	#	#	#	#	#
3.	#	#	#	#	#	#	#
4.	#	#	#	#	#	#	#
5.	#	#	#	#	#	#	#
6.	#	#	#	#	#	#	#
7. None Selected						#	#
8 Out of Range						#	#

	L	H		
Panic Value:	#	#	Unit: U/l	Decimal Places: 2

Calibration Specific
General | ISE

Test name: **ACP** Type: **Serum**

Calibration Type: **3AB** Formula: **Polygonal** Counts: **3** Process: **CONC**

	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1:	#		**	-2.0000	2.5000
Point 2:	#		*	-2.0000	2.5000
Point 3:	#		*	-2.0000	2.5000
Point 4:					
Point 5:					
Point 6:					
Point 7:					

1-Point Cal.Point: [ ] [ ] with CONC-0 Slope Check: **None** Advanced Calibration: #

MB Type Factor: Calibration 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: **Serum** Operation: **Yes**

Sample: Volume	15	µL	Dilution	0	µL	Pre-Dilution Rate:	1		
Reagents: R1 Volume	200	µL	Dilution	0	µL	Min OD		Max OD	
R2 Volume	0	µL	Dilution	0	µL	L	-2.0000	H	2.5000
						Reagent OD Limit:			
Wavelength: Pri.	410		Sec.	660		First L	-2.0000	First H	2.5000
Method:	RATE					Last L	-2.0000	Last H	2.5000
Reaction Slope:	+					Dynamic Range:			
Measuring Point 1: First	10		Last	25		L		H	
Measuring Point 2: First			Last			Correlation Factor:			
Linearity:	15	%				A	1.000	B	0.000
No-Lag-Time:						On-board Stability Period:			

Specific Test Parameters

General | LIH | ISE | Range

Test name: **ACPnp** Type: **Serum**

Value/Flag: # Level L: # Level H: #

Normal Ranges:

	Sex	Age L Year	Age L Month	Age H Year	Age H Month	L	H
1.	#	#	#	#	#	#	#
2.	#	#	#	#	#	#	#
3.	#	#	#	#	#	#	#
4.	#	#	#	#	#	#	#
5.	#	#	#	#	#	#	#
6.	#	#	#	#	#	#	#
7.	None Selected					#	#
8	Out of Range					#	#

	L	H		
Panic Value:	#	#	Unit: **U/l**	Decimal Places: **2**

Calibration Specific

General | ISE

Test name: **ACPnp** Type: **Serum**

Calibration Type: **3AB** Formula: **Polygonal** Counts: **1** Process: **CONC**

	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1:	#		**	**-2.0000**	**2.5000**
Point 2:	#		*	**-2.0000**	**2.5000**
Point 3:	#		*	**-2.0000**	**2.5000**
Point 4:					
Point 5:					
Point 6:					
Point 7:					

1-Point Cal.Point: [ ] [ ] with CONC-0 Slope Check: **None** Advanced Calibration: #

MB Type Factor: Calibration Stability Period:

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

CALCULATION OF ACP-P (prostatic acid phosphatase)
ACP-P [U/l] = ACP - ACP-NP

REFERENCE VALUES [4]
ACP

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

ACP-P

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.

QUALITY 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.
For the calibration of automatic analysers systems the CORMAY 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/l (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**

ACP

Repeatability (run to run) n = 20	Mean [U/l]	SD [U/l]	CV [%]
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/l]	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

Repeatability (run to run) n = 20	Mean [U/l]	SD [U/l]	CV [%]
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) n = 20	Mean [U/l]	SD [U/l]	CV [%]
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/l;
R = 0.997 (R – correlation coefficient)

ACP-NP
y = 1.1325 x - 0.09887 U/l;
R = 0.998 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

1. NCCLS Document: "Procedures for the Collection of Arterial Blood specimens; Approved standard- Third Edition (1999)".
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3. 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).
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