Cat. No 4-549

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

## HC – 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 | 6 x 20 ml |
| REAGENT 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 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.
- A slight pink coloration of working reagents ACP and ACP-NP does not affect the reagents performance.

### 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 20 µl 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 analyser Hitachi 911/912.

Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:

1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

### 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.

### ACP-NP ASSAY

**Working reagent ACP-NP:** 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

### 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 – 0.153 |

**ACP-P**

| serum (tartrate inhibition) | U/l | µkat/l |
|---|---|---|
| male | 0.2 – 3.5 | 0.003 – 0.058 |
| female | 0 – 0.8 | 0 – 0.013 |

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

### QUALITY CONTROL

For internal quality control 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 the calibration of automatic analysers systems the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) is recommended. **Calibrator and 0.9% NaCl** should be used for calibration.

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 the automatic analyser Hitachi 704. 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 activity higher 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)".
2. Kaplan, L.A., Pesce A.J.,: " Clinical Chemistry", Mosby Ed. (1996).
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).
4. Tietz N.W.: Textbook of Clinical Chemistry, 3rd ed., W. B. Saunders Company, Philadelphia, 1828 (1999).



**Date of issue:** 07. 2012.



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07/12/07/12