Cat. No 7-449

DIAGNOSTIC KIT FOR DETERMINATION OF TOTAL ACID PHOSPHATASE ACTIVITY

A-400 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).

REAGENTS
Package

REAGENT 1a	6 x 20 ml
REAGENT 1b	6 vials (powder)
ACETIC ACID SOLUTION (acetic acid 0.1 mol/l)	1 x 3 ml

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 reagent ACP 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

Warnings and notes
- Product for in vitro diagnostic use only.
- The reagents must be used only for the intended purpose, by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- 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 reagent ACP 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 BS-400 and BS-480.
For reagent blank deionized water is recommended.
Actions required:
BS-400
When performing assays at analyser BS-400, there is a probability of **cross-contamination** affecting the tests results: CALCIUM – ACP. To avoid this effect follow the recommendations contained in the advisory note **"Carry-over – Preventive Actions "**.

ASSAY
Working reagent: 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.

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

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 the calibration of automatic analyser system BS-400 the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) or LEVEL 2 (Cat. No 5-175; 5-177) is recommended. Deionised water should be used as a calibrator 0.
For the calibration of automatic analyser system BS-480 the CORMAY MULTICALIBRATOR LEVEL 2 (Cat. No 5-175; 5-177) is recommended. Deionised water should be used as a calibrator 0.
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 automatic analysers BS-480 and/or Hitachi 704. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:**

2.05 U/l (0.034 µkat/l)

- **Linearity:**

up to 58.3 U/l (0.97 µkat/l)
For higher activity than 58.3 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**

Repeatability (run to run) (n=10)	Mean [U/l]	SD [U/l]	CV [%]
level 1	20.12	1.17	5.83
level 2	35.11	0.45	1.27
Reproducibility (day to day) (n=10)	Mean [U/l]	SD [U/l]	CV [%]
level 1	21.07	1.29	6.13
level 2	33.49	2.13	6.37

- **Method comparison**

A comparison between CORMAY reagent (y) and another commercially available assay (x) using 60 samples gave following results:
y = 1.0162 x + 0.10151 U/l;
R = 0.997 (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).

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