ACP

cobas®

Acid phosphatase

Order information

REF	CONTENT		Analyzer(s) on which kit(s) can be used
04375351 190	Acid phosphatase ([1] 8 x 17 mL, [1a] →8 x 17 mL, [2] →4 x 17 mL, [3] 2 x 10 mL)		Roche/Hitachi MODULAR P
04375335 190	Acid phosphatase ([1] →8 x 10 mL, [1a] 1 x 82 mL, [2] →4 x 10 mL, [3] 1 x 10 mL)		Roche/Hitachi MODULAR P Roche/Hitachi 902
10759350 190	Calibrator f.a.s. (12 x 3 mL)	Code 401	
10171743 122	Precinorm U (20 x 5 mL)	Code 300	
10171735 122	Precinorm U (4 x 5 mL)	Code 300	
12149435 122	Precinorm U plus (10 x 3 mL)	Code 300	
10171778 122	Precipath U (20 x 5 mL)	Code 301	
10171760 122	Precipath U (4 x 5 mL)	Code 301	
12149443 122	Precipath U plus (10 x 3 mL)	Code 301	
05117003 190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 391	
05947626 190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 391	
05117216 190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 392	
05947774 190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 392	

Some analyzers and kits shown may not be available in all countries. For additional system applications, contact your local Roche Diagnostics representative.

English

System information

Roche/Hitachi MODULAR P analyzer:

ACN 021; ACN 022 (non-prostatic ACP).

Intended use

In vitro test for the quantitative determination of acid phosphatase and prostatic acid phosphatase in human serum on Roche automated clinical chemistry analyzers.

Summary[1,2,3]

Serum acid phosphatase consists of 5 isoenzymes that originate mainly from erythrocytes, platelets, spleen and liver reticuloendothelial cells, the kidneys, bone, and prostate epithelial cells. Prostatic acid phosphatase isoenzyme 2 is formed mainly, but not exclusively, in the prostate.

In general, total acid phosphatase and prostatic acid phosphatase levels increase in the presence of progressive and metastasizing prostate carcinoma, the increase being dependent upon the disease stage in 80 % of patients with metastasizing prostate cancer. The percentage increase at each stage depends on the classification (pathological or clinical).

Increased acid phosphatase levels occur in Gaucher's disease, Niemann-Pick disease, 1-2 days after prostate surgery, biopsy, manipulation or catheterization, and in the presence of benign prostate hypertrophy, prostatitis and prostate infarction.

The assay used here is a modification of the method described by Hillmann. Addition of 1,5-pentanediol increases the activity of prostatic acid phosphatase.

Test principle[3]

Colorimetric test

- Sample and addition of R1 and start of reaction:

$$\text{1-naphthyl phosphate} + H_2O \xrightarrow[\text{phosphatase}]{\text{acid}} \text{1-naphthol} + \text{phosphate}$$

$$\text{1-naphthol} + \text{fast red TR}^a \longrightarrow \text{azo dye}$$

The 1-naphthol released during the enzymatic hydrolysis of 1-naphthyl phosphate is converted to an azo dye by coupling with diazotized fast red TR[a]. The tartrate is used as a specific inhibitor for prostatic acid phosphatase.

a) Fast red TR = 2-amino-5-chlorotoluene

Reagents - working solutions

R1 (Bottles 1, 1a and 2)
Citrate buffer: 150 mmol/L, pH 4.8; 1-naphthyl phosphate: 12.1 mmol/L; fast red TR salt: 1.2 mmol/L; 1,5-pentanediol: 220 mmol/L; detergent: 3.3 mL/L
(Additionally for non-prostatic acid phosphatase determination: sodium tartrate: 100 mmol/L.)

3 Acetic acid: 0.8 mol/L.

Precautions and warnings

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.
Safety data sheet available for professional user on request.

Reagent handling

04375351 190

Total acid phosphatase

R1: Connect one bottle 1 to one bottle 1a using the enclosed adapter, and dissolve the substrate/chromogen mixture completely in the buffer.

Non-prostatic acid phosphatase

R1: Connect one bottle 1 to one bottle 1a using the enclosed adapter, and dissolve the substrate/chromogen mixture completely in the buffer. Add a reagent tablet from bottle 2 and dissolve by gently swirling. Affix one of the enclosed barcoded labels exactly over the bottle label.

Carefully rinse the adapter with water after use.

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Total acid phosphatase

R1: Dissolve the contents of one bottle 1 by adding buffer from bottle 1a up to the mark (10 mL).

Non-prostatic acid phosphatase

R1: Dissolve the contents of one bottle 1 by adding buffer from bottle 1a up to the mark (10 mL). Then add a reagent tablet from bottle 2 and dissolve by gently swirling.

Storage and stability

Unopened kit components: Up to the expiration date at 2-8 °C

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R1: 5 days opened and refrigerated on the analyzer

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R1: 5 days opened and refrigerated on the analyzer
24 hours open and without refrigeration

Store the reagent protected from light.

Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimen listed below was tested and found acceptable.
Serum.

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Perform determinations on the samples immediately. Samples which cannot be examined immediately should be stabilized as follows: Add 1 drop (30 µL) of solution from bottle 3 to 1.0 mL of serum and mix.

Stability:[4] 8 days at 15-25 °C

8 days at 2-8 °C

4 months at (-15)-(-25) °C

Centrifuge samples containing precipitates before performing the assay.

Materials provided

See “Reagents – working solutions” section for reagents.

Materials required (but not provided)

- See “Order information” section
- General laboratory equipment
- 0.9 % NaCl

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator’s manual for analyzer-specific assay instructions.

The performance of applications not validated by Roche is not warranted and must be defined by the user.

Calibration

Traceability: This method has been standardized against the Roche system reagent using calibrated pipettes together with a manual photometer providing absolute values and the substrate-specific absorptivity, ε.

Total acid phosphatase

S1: 0.9 % NaCl

S2: C.f.a.s. Use the assigned ACP value.

Non-prostatic acid phosphatase

S1: 0.9 % NaCl

S2: C.f.a.s. Use the assigned ACP-NPP value.

Calibration frequency

2-point calibration is recommended

- as required following quality control procedures

Quality Control

For quality control, use control materials as listed in the "Order information" section.

In addition, other suitable control material can be used.

The control intervals and limits should be adapted to each laboratory’s individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Calculation

A) Total acid phosphatase: See instrument printout.

B) Prostatic acid phosphatase:

$\text{Activity}_{\text{Prostatic acid phosphatase}} =$

$\text{Activity}_{\text{Total acid phosphatase}} - \text{Activity}_{\text{Non-prostatic acid phosphatase}}$

When measuring total acid phosphatase (ACP) on one channel and non-prostatic acid phosphatase (NPP) on another channel, the prostatic acid phosphatase can be determined directly. The instrument-specific program prints out the difference between the two determinations as prostatic acid phosphatase.

Conversion factor: U/L x 0.0167 = µkat/L

Limitations - interference

Criterion: Recovery within ± 10 % of initial value.

Icterus:[5] No significant interference up to an I index of 1 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 1 mg/dL or 17.1 µmol/L).

Hemolysis:[5] No significant interference up to an H index of 100 (approximate hemoglobin concentration: 100 mg/dL or 62.1 µmol/L).

Lipemia (Intralipid):[5] No significant interference up to an L index of 200. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Cefoxitin causes artificially high results in the determination of acid phosphatase and non-prostatic acid phosphatase. Ascorbic acid and doxycycline cause artificially high results in the determination of non-prostatic acid phosphatase.

In very rare cases, gammopathy, in particular type IgM (Waldenström’s macroglobulinemia), may cause unreliable results.[6]

The addition of stabilizer to the sample interferes with the determination of other parameters.

Roche/Hitachi 902 analyzers: If, in addition to ACP, calcium is also determined on the analyzer, perform the ACP determination in batch mode with a separate cuvette ring.

For diagnostic purposes, the results should always be assessed in conjunction with the patient’s medical history, clinical examination and other findings.

ACTION REQUIRED

Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on Roche/Hitachi analyzers. Refer to the latest version of the carry-over evasion lists and the operator’s manual for further instructions. US users refer to the Special Wash Programming document (located on MyLabOnline website) and the operator’s manual for special wash instructions.

Where required, special wash/carry-over evasion programming must be implemented prior to reporting results with this test.

Limits and ranges

Measuring range

Roche/Hitachi MODULAR P analyzers

0.5-200 U/L (0.01-3.34 µkat/L)

Roche/Hitachi 902 analyzer

0.5-200 U/L (0.01-3.34 µkat/L)

Determine samples with higher acid phosphatase activities via the rerun function.

On instruments without rerun function, manually dilute samples having higher activities with 0.9 % NaCl or distilled/deionized water (e.g. 1 + 2). Multiply the result by the appropriate factor (e.g. 3).

Roche/Hitachi MODULAR P analyzers

Determine samples having higher activities via the rerun function. Dilution of samples via the rerun function is a 1:3 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 3.

Lower limits of measurement

Lower detection limit of the test

0.5 U/L (0.01 µkat/L)

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The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 3 standard deviations above that of the lowest standard (standard 1 + 3 SD, repeatability, n = 21).

Expected values

Total acid phosphatase (37 °C)[7]

Men: < 6.6 U/L (< 0.110 µkat/L)

Women: < 6.5 U/L (< 0.108 µkat/L)

Prostatic acid phosphatase (37 °C)[7]

Men: < 3.5 U/L (< 0.058 µkat/L)

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Specific performance data

Representative performance data on the analyzers are given below. Results obtained in individual laboratories may differ.

Precision

Precision was determined using human samples and controls in an internal protocol with repeatability (n = 21) and intermediate precision (3 aliquots per run, 1 run per day, 21 days). The following results were obtained:

	Repeatability		
Sample	Mean		CV
	U/L	µkat/L	%
Control serum I	13.3	0.22	1.0
Control serum II	24.1	0.40	0.4
Control serum III	28.0	0.45	0.5

	Intermediate precision		
Sample	Mean		CV
	U/L	µkat/L	%
Control serum I	13.0	0.22	3.5
Control serum II	23.9	0.40	1.4
Control serum III	28.0	0.47	1.3

Method comparison

A comparison of the acid phosphatase assay using the Roche acid phosphatase reagent on a Roche/Hitachi 917 analyzer (y) with the same assay on a Roche/Hitachi 717 analyzer (x) gave the following correlation (U/L):

Passing/Bablok[8]	Linear regression
y = 1.008x - 0.404	y = 0.979x - 0.290
τ = 0.83	r = 0.993

Number of samples measured: 118

The sample activities were between 0.37 and 44.2 U/L (0.006-0.737 µkat/L).

References

1 Tietz NW, ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia, PA: WB Saunders Company 1995;516-519.

2 Heller JE. Prostatic acid phosphatase: Its current clinical status. J Urol 1987;137(6):1091-1103.

3 Hillmann G. Z klin Chem u klin Biochem 1971;9:273.

4 Guder WG, Narayanan S, Wisser H, et al. List of Analytes; Preanalytical Variables. Brochure in: Samples: From the Patient to the Laboratory. Darmstadt: GIT-Verlag 1996.

5 Glick MR, Ryder KW, Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation. Clin Chem 1986;32:470-475.

6 Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007;45(9):1240-1243.

7 Junge W, Thormeyer I, Schlottmann A, et al. Determination of Reference Values for Acid Phosphatase using a New Photometric Assay. Pecs, Hungary: 3rd Alpe-Adria Congress on Clinical Chemistry and Laboratory Medicine. September 7-9, 1994.

8 Bablok W, Passing H, Bender R, et al. A general regression procedure for method transformation. Application of linear regression procedures for method comparison studies in clinical chemistry, Part III. J Clin Chem Clin Biochem 1988 Nov;26(11):783-790.

Instrument settings

Users of Roche/Hitachi MODULAR analyzers: Enter the application parameters via the barcode sheet.

Users of Roche/Hitachi 902 analyzer: Calculate the prostate phosphatase (ACPP) by taking the difference of the two determinations:
ACPP = ACP – NPP

No.	<Calculated Test>	
1	Test Name	[ACPP]
2	Formula	[(aA–bB)]
3	Test A	[ACP]
4	Test B	[NPP]
5	Factor a	[1]
6	Factor b	[1]
7	Expect. Value L	[_._]
8	Expect. Value H	[_._]

Roche/Hitachi 902 analyzer

No.	<Chemistry>		
1	Test Name	**ACP**	**NPP**
2	Assay Code (Mthd)	2-Point Rate	2-Point Rate
3	Assay Code (2. Test)	0	0
4	Reaction Time	10	10
5	Assay Point 1	22	22
6	Assay Point 2	35	35
7	Assay Point 3	0	0
8	Assay Point 4	0	0
9	Wavelength (SUB)	700	700
10	Wavelength (MAIN)	415	415
11	Sample Volume	20	20
12	R1 Volume	250	250
13	R1 Pos.	.....	.....
14	R1 Bottle Size	Small	Small
15	R2 Volume	0	0
16	R2 Pos.	0	0
17	R2 Bottle Size	Small	Small
18	R3 Volume	0	0
19	R3 Pos.	0	0
20	R3 Bottle Size	Small	Small
21	Calib. Type (Type)	Linear	Linear
22	Calib. Type (Wght)	0	0
23	Calib. Conc. 1	0.00	0.00
24	Calib. Pos. 1	.....	.....
25	Calib. Conc. 2	.....	.....

ACP

Acid phosphatase

26	Calib. Pos. 2	.....	.....
27	Calib. Conc. 3	0	0
28	Calib. Pos. 3	0	0
29	Calib. Conc. 4	0	0
30	Calib. Pos. 4	0	0
31	Calib. Conc. 5	0	0
32	Calib. Pos. 5	0	0
33	Calib. Conc. 6	0	0
34	Calib. Pos. 6	0	0
35	S1 ABS	0	0
36	K Factor	10000	10000
37	K2 Factor	10000	10000
38	K3 Factor	10000	10000
39	K4 Factor	10000	10000
40	K5 Factor	10000	10000
41	A Factor	0	0
42	B Factor	0	0
43	C Factor	0	0
44	SD Limit	0.1	0.1
45	Duplicate Limit	50	50
46	Sens. Limit	0	0
47	S1 Abs. Limit (L)	-32000	-32000
48	S1 Abs. Limit (H)	32000	32000
49	Abs. Limit	15000	10000
50	Abs. Limit (D/I)	Increase	Increase
51	Prozone Limit	0	0
52	Proz. Limit (Upp/Low)	Lower	Lower
53	Prozone (Endpoint)	35	35
54	Expect. Value (L)	.....	.....
55	Expect. Value (H)	.....	.....
56	Instr. Fact. (a)	1	1
57	Instr. Fact. (b)	0	0
58	Key setting	.....	.....

..... Data entered by the operator

For further information, please refer to the appropriate operator's manual for the analyzer concerned, the respective application sheets and method sheets of all necessary components.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

CONTENT	Contents of kit
REAGENT	Reagent
CALIBRATOR	Calibrator
→	Volume after reconstitution or mixing

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