ACID PHOSPHATASE

This package insert contains information to run the Acid Phosphatase assay on the ARCHITECT *c* Systems™ and the AEROSET System.

NOTE: Changes Highlighted

NOTE: This package insert must be read carefully prior to product use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Customer Support

United States:	**1-877-4ABBOTT**
Canada:	**1-800-387-8378 (English speaking customers)**
	1-800-465-2675 (French speaking customers)
International:	**Call your local Abbott representative**

Symbols in Product Labeling

CONC	Concentration	REF	Catalog number/List number
EC REP	Authorized Representative in the European Community	SN	Serial number
INGRED	Ingredients		Consult instructions for use
IVD	In vitro diagnostic medical device		Manufacturer
LOT	Batch code/Lot number	°C	Temperature limitation
LIQUID STABILIZER	Liquid Stabilizer		Use by/Expiration date
R1	Reagent 1		

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NAME

ACID PHOSPHATASE

INTENDED USE

The Acid Phosphatase assay is used for the quantitation of acid phosphatase in human serum.

NOTE: This method is for the measurement of total acid phosphatase, and is not specific for prostatic acid phosphatase enzyme.

SUMMARY AND EXPLANATION OF TEST

The greatest concentration of acid phosphatase (ACP) activity occurs in liver, spleen, milk, erythrocytes, platelets, bone marrow, and the prostate gland. The last is the richest source, and it contributes a small proportion of the enzyme present in sera from healthy males.[1] Increasing levels of ACP are consistent with prostatic cancer.

The optimal pH for the individual ACPs varies depending on the tissues from which they are obtained. The observed pH optimum also varies with the substrate on which the enzyme acts; the more acidic the substrate, the lower the pH at which maximum activity is obtained. The ACPs are unstable, especially at temperatures above 37°C and at pH levels above 7.0. Some of the enzyme forms in serum (especially the prostatic enzyme) are particularly labile and more than 50% of the ACP activity may be lost in 1 hour at room temperature. Acidification of the serum specimen to a pH below 6.5 aids in stabilizing the enzyme.[1]

PRINCIPLES OF PROCEDURE

Acid Phosphatase catalyzes the hydrolysis of alpha-naphthylphosphate, liberating the alpha-naphthol and phosphate. The alpha-naphthol is then coupled with diazotized 2-amino-5-chlorotoluene (Fast Red TR) to form diazo dye which has a strong absorbance at 405 nm. The increase in absorbance is directly proportional to the level of ACP in the sample.[2] The diazo dye is measured bichromatically at 412/660 nm on the ARCHITECT *c* 8000 System and the AEROSET System; 416/660 nm on the ARCHITECT *c* 16000 System.

Methodology: Alpha-naphthylphosphate

REAGENTS

Reagent Kit

REF 9D87 Acid Phosphatase is supplied as a single reagent kit which contains:

- R1 6 x 20 mL
- LIQUID STABILIZER 2 x 20 mL
- Funnels (6)
- Bar code labeled cartridges (6)

Estimated tests per kit: 623

Calculation is based on the minimum reagent fill volume per kit.

Reactive Ingredients		Concentration
R1	α-Naphthylphosphate Disodium Salt	3 mmol/L
	4-Chloro-2-Methylbenzenediazonium Salt	1 mmol/L
LIQUID STABILIZER	Acetate Buffer	3 mol/L

REAGENT HANDLING AND STORAGE

Reagent Handling

Remove air bubbles, if present in the reagent cartridge, with a new applicator stick. Alternatively, allow the reagent to sit at the appropriate storage temperature to allow the bubbles to dissipate. To minimize volume depletion, do not use a transfer pipette to remove the bubbles.

CAUTION: Reagent bubbles may interfere with proper detection of reagent level in the cartridge, causing insufficient reagent aspiration which could impact results.

Reagent Storage

Unopened reagents are stable until the expiration date when stored at 2 to 8°C. Do not pool reagents.

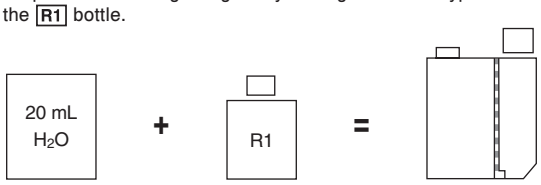
Reconstituted Acid Phosphatase reagent R1 is stable for 5 days when stored at 2 to 8°C and protected from light. R1 is stable for 5 days uncapped, onboard, and protected from light.

Liquid Stabilizer reagent is a ready-to-use liquid and is stable until the expiration date when stored at 2 to 8°C.

REAGENT HANDLING AND STORAGE (Continued)

Instructions for Use

1. Remove the R1 reagent cap.
2. Prepare the Working Reagent by adding 20 mL of Type II water to the R1 bottle.



Working Reagent 1

3. Replace the R1 reagent cap and mix by gentle inversion until completely dissolved.
4. Pour the contents into one of the empty bar code labeled cartridges provided with the reagent kit.
   Remove air bubbles, if present in the cartridge, with a new applicator stick.
5. Place the cartridge in Reagent Supply Center 1.

WARNINGS AND PRECAUTIONS

Precautions for Users

1. For in vitro diagnostic use.
2. Do not use components beyond the expiration date.
3. Do not mix materials from different kit lot numbers.
4. Do not mix reagents prepared at different times.
5. Do not reuse the reagent containers, bottles, caps, or plugs due to the risk of contamination and the potential to compromise reagent performance.
6. **CAUTION: Bottle stopper contains dry natural rubber.**
7. **CAUTION:** This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens.[3] Biosafety Level 2[4] or other appropriate biosafety practices[5,6] should be used for materials that contain or are suspected of containing infectious agents.

For reagents not classified as dangerous per European Directive 1999/45/EC as amended, safety data sheet available for professional user on request.

SPECIMEN COLLECTION AND HANDLING

Suitable Specimens

Serum is the acceptable specimen.

Serum samples must be stabilized (i.e., acidified) by the addition of 50 µL of Liquid Stabilizer for every 1 mL of serum.

Serum: Use acidified, nonhemolyzed, nonicteric, nonlipemic serum with or without gel barrier collected by standard venipuncture techniques in glass or plastic tubes. Ensure complete clot formation has taken place prior to centrifugation. Separate from red blood cells or gel as soon after collection as possible.

Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may take longer to complete their clotting processes. Fibrin clots may subsequently form in these sera and the clots could cause erroneous test results.

NOTE: Use of sample interference indices may assist in the determination of sample integrity. Refer to instrument-specific *Sample Interference Indices (HIL)* application sheets.

Refer to the specimen collection tube manufacturer's instructions for processing and handling requirements.

For total sample volume requirements, refer to the instrument-specific ASSAY PARAMETERS section of this package insert and *Section 5* of the instrument-specific operations manual.

Specimen Storage

Serum: Separated, acidified serum should be analyzed immediately.

Temperature	Maximum Storage	Bibliographic Reference
2 to 8°C	3 days	7, 8
-20°C	6 months	7, 8
-70°C	indefinitely	9

NOTE: Stored specimens must be inspected for particulates. If present, mix and centrifuge the specimen to remove particulates prior to testing.

PROCEDURE

Materials Provided

REF 9D87 Acid Phosphatase Reagent Kit

Materials Required but not Provided

- Control Material
- Type II Water
- Saline (0.85% to 0.90% NaCl) for specimens that require dilution

Assay Procedure

For a detailed description of how to run an assay, refer to *Section 5* of the instrument-specific operations manual.

Specimen Dilution Procedures

The ARCHITECT *c* Systems and the AEROSET System have automatic dilution features; refer to *Section 2* of the instrument-specific operations manual for additional information.

Serum: Specimens with acid phosphatase values exceeding 87.9 U/L are flagged and may be diluted using the Automated Dilution Protocol or the Manual Dilution Procedure.

Automated Dilution Protocol

If using the Automated Dilution Protocol, the system performs a dilution of the specimen and automatically corrects the enzyme activity value by multiplying the result by the appropriate dilution factor. To set up the automatic dilution feature, refer to *Section 2* of the instrument-specific operations manual for additional information.

Manual Dilution Procedure

Manual dilutions should be performed as follows:

- Use saline (0.85% to 0.90% NaCl) to dilute the sample.
- The operator must enter the dilution factor in the patient or control order screen. The system uses this dilution factor to automatically correct the enzyme activity value by multiplying the result by the entered factor.
- If the operator does not enter the dilution factor, the result must be multiplied by the appropriate dilution factor before reporting the result.

NOTE: If a diluted sample result is flagged indicating it is less than the linear low limit, do not report the result. Rerun using an appropriate dilution.

For detailed information on ordering dilutions, refer to *Section 5* of the instrument-specific operations manual.

CALIBRATION

Calibration is stable for approximately 5 days (120 hours) and is required with each change in reagent lot number. Verify calibration with at least two levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary.

A calibration factor (1046.5) must be entered.

- ARCHITECT *c* Systems—**Configure assay parameters** window, **Calibration** view
- AEROSET System—**Assay Configuration** screen, **Calibration** page

For a detailed description of how to calibrate an assay, refer to *Section 6* of the instrument-specific operations manual.

QUALITY CONTROL

The following is the recommendation of Abbott Laboratories for quality control. As appropriate, refer to your laboratory standard operating procedure(s) and/or quality assurance plan for additional quality control requirements and potential corrective actions.

- Two levels of controls (normal and abnormal) are to be run every 24 hours.
- Some control material may require addition of Liquid Stabilizer.
- If more frequent control monitoring is required, follow the established quality control procedures for your laboratory.
- If quality control results do not meet the acceptance criteria defined by your laboratory, patient values may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary.
- Review quality control results and acceptance criteria following a change of reagent lot.

RESULTS

Refer to the instrument-specific operations manual for information on results calculations.

- **ARCHITECT System Operations Manual**—*Appendix C*
- **AEROSET System Operations Manual**—*Appendix A*

Representative performance data are given in the EXPECTED VALUES and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert. Results obtained in individual laboratories may vary.

LIMITATIONS OF THE PROCEDURE

Refer to the SPECIMEN COLLECTION AND HANDLING and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert.

The performance characteristics of Acid Phosphatase on an analyzer other than the ARCHITECT *c* Systems or the AEROSET System must be validated and verified.

EXPECTED VALUES

Reference Range

Serum[2]

	Range (U/L)
Adult	0.0 to 6.0

A study was conducted using 230 serum samples from 115 female and 115 male volunteers. Data were analyzed as described by Solberg[10] and Clinical and Laboratory Standards Institute (CLSI) protocol NCCLS C28-A.[11] From this study, 95% of male specimens for acid phosphatase fell within 2.2 to 4.2 U/L, with male samples ranging from 2.2 to 4.4 U/L. For female specimens, 95% of acid phosphatase specimens fell within 1.8 to 4.2 U/L, with female samples ranging from 1.6 to 4.5 U/L. It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity

Acid Phosphatase is linear up to 87.9 U/L. Linearity was verified using CLSI protocol NCCLS EP6-P.[12]

Limit of Detection (LOD)

The LOD for Acid Phosphatase is 0.7 U/L. The LOD is the mean concentration of an analyte-free sample + 2 SD, where SD = the pooled, within-run standard deviation of the analyte-free sample. A study performed on an ARCHITECT *c* System and an AEROSET System produced an LOD for Acid Phosphatase of 0.38 U/L.

Limit of Quantitation (LOQ)

The LOQ for Acid Phosphatase is 0.73 U/L. The LOQ is the analyte concentration at which the CV = 20%.

Interfering Substances

Interference studies were conducted using CLSI protocol NCCLS EP7-P.[13] Interference effects were assessed by Dose Response and Paired Difference methods, at the medical decision level of the analyte. Expected values are for total acid phosphatase.

Interfering Substance	Interferent Concentration		N	Target (U/L)	Observed (% of Target)
Bilirubin	3.8 mg/dL	(65 µmol/L)	4	5.9	54.4
Hemoglobin	62 mg/dL	(0.62 g/L)	4	6.5	48.5
Human Triglyceride	200 mg/dL	(2.26 mmol/L)	4	6.0	85.3
Intralipid	125 mg/dL	(1.25 g/L)	4	6.5	95.1
	250 mg/dL	(2.50 g/L)	4	6.5	84.0

Do not use samples with elevated bilirubin, hemoglobin, or triglyceride. These substances showed greater than 10% interference.

Bilirubin solutions at the above concentrations were prepared by addition of a bilirubin stock to human serum pools. Hemoglobin solutions at the above concentrations were prepared by addition of hemolysate to human serum pools. Human triglyceride solutions at the above concentrations were prepared by mixing an elevated triglyceride human serum pool with a normal triglyceride human serum pool. Intralipid solutions at the above concentrations were prepared by addition of Intralipid to human serum pools.

SPECIFIC PERFORMANCE CHARACTERISTICS (Continued)

Precision

The imprecision of the Acid Phosphatase assay is ≤ 7.3% Total CV. Representative data from studies using CLSI protocol NCCLS EP5-A[14] are summarized below.

Control		Level 1	Level 2
N		80	80
Mean (U/L)		3.5	30.3
Within Run	SD	0.08	0.21
	%CV	2.3	0.7
Between Run	SD	0.06	0.66
	%CV	1.7	2.2
Between Day	SD	0.11	0.45
	%CV	3.2	1.5
Total	SD	0.15	0.82
	%CV	4.3	2.7

Method Comparison

Correlation studies were performed using CLSI protocol NCCLS EP9-A.[15]

Serum results from the Acid Phosphatase assay on an AEROSET System were compared with those from a commercially available alpha-naphthylphosphate methodology.

Serum results from the Acid Phosphatase assay on an ARCHITECT *c* System were compared with the Acid Phosphatase assay on an AEROSET System.

	AEROSET vs. Comparative Method	ARCHITECT vs. AEROSET
N	72	83
Y - Intercept	0.417	0.208
Correlation Coefficient	0.995	0.999
Slope	1.057	0.980
Range (U/L)*	1.9 to 50.8	2.10 to 75.30

*AEROSET Range

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TRADEMARKS

ARCHITECT®

Acid Phosphatase Serum—Conventional and SI Units

Configure assay parameters — General

● General O Calibration O SmartWash O Results O Interpretation

Assay: **ACP** Type: **Photometric** Version: †
Number: **1047**

● Reaction definition O Reagent / Sample O Validity checks

Reaction mode: **Rate up**

	Primary		Secondary		Read times
Wavelength:	††	/	660	Main:	**16 – 24**
Last required read:	**24**			Flex:	___–___
Absorbance range:	**0.0100 – 2.0000**			Color Correction:	___–___
Sample blank type:	**None**				

O Reaction definition ● Reagent / Sample O Validity checks

R1

Reagent: **ACP00** Reagent volume: **150**
Diluent: **Saline** Water volume: ___
Diluent dispense mode: **Type 0** Dispense mode: **Type 0**

Dilution name	Sample	Diluted sample	Diluent	Water		Dilution factor	Default dilution
STANDARD :	**12.0**	___	___	___	=	**1:1.00**	●
_____ :	___	___	___	___	=		O
_____ :	___	___	___	___	=		O

O Reaction definition O Reagent / Sample ● Validity checks

Reaction check: **None**

Rate linearity %: **15**

Configure assay parameters — Calibration

O General ● Calibration O SmartWash O Results O Interpretation

Assay: **ACP** Calibration method: **Factor**
Factor: **1046.5000**

● Calibrators O Volumes O Intervals O Validity checks

Calibrator set: **None** Calibrator level: **Blank:** Concentration: **Water** **0.0**

Replicates: **3** [Range 1 – 3]

O Calibrators ● Volumes O Intervals O Validity checks

Calibrator:

	Calibrator level	Sample	Diluted sample	Diluent	Water
Blank:	**Water**	**12.0**	___	___	___

O Calibrators O Volumes ● Intervals O Validity checks

Calibration intervals:
Full interval: **120** (hours)

O Calibrators O Volumes O Intervals ● Validity checks

Blank absorbance range: _____ – _____

Configure assay parameters — SmartWash

O General O Calibration ● SmartWash O Results O Interpretation

Assay: **ACP**

COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates
Cuvette	**Trig**	**10% Detergent B*** **	**345**	

*** Select "**Detergent B**" for software prior to Version 2.2.

Configure assay parameters — Results

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **ACP** Result units: **U/L**
Assay defaults:
Low-Linearity: **0.8**‡‡
High-Linearity: **87.9**
Gender and age specific ranges:

GENDER	AGE (UNITS)	NORMAL	EXTREME
Either	**0 – 130 (Y)**	**0.0 – 6.0**	

Configure result units

Assay: **ACP**
Version: †

Result units: **U/L**
Decimal places: **1** [Range 0 – 4]

Correlation factor: **1.0000**
Intercept: **0.0000**

† Due to differences in instrument systems and unit configurations, version numbers may vary.
†† The *c*8000 Primary Wavelength is 412 nm; the *c*16000 System Primary Wavelength is 416 nm.
‡‡ The linear low value (Low-Linearity) is LOQ rounded up to the number of decimal places defined in the decimal places parameter field.

AEROSET®

Acid Phosphatase Serum—Conventional and SI Units

Assay Configuration: Outline Page

Assay Name	Assay #	Line
ACP	47	A-Line

Quantitative Ranges

Min Text	Min	Panic-L	L-Reference-H	Panic-H	Max	Max Text
< 0.4*	0.4*	0.0	0.0	6.0	0.0	87.9*	> 87.9*

0.8** **L-Linear Range-H** 87.9

Reference Ranges*

Age	Male	Female
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0

Qualitative Ranges N/A

Assay Configuration: Base Page

Reaction Mode	Wavelength-Prim/Sec	Read time-Main/Flex	Linearity %
RATE UP	412 / 660	16 – 24 / 0 – 0	15
Sample Blank Test	**Blank Read Time**	**Abs Window**	**Abs Limits**
_____ (___)	0 – 0	0 – 0	0.01 – 2.0

	S.Vol	DS.Vol	D.Vol	W.Vol		
Standard	12.0	0.0	0	0		**Rgt Name/Pos**
Dil 1	12.0	0.0	0	0	**Diluent:**	_____ _–__*
Dil 2	12.0	0.0	0	0	**Type#**	0

	Rgt Name/Pos	R.Vol	W.Vol	Type#
Reagent 1	ACP0011 – ___*	150	0	0

Reaction Check	Read Time – A/B	Range	Minimum
_____	1 – 1 / 1 – 1	0.0 – 0.0	0.0

Factor/Intercept	Decimal Places	Units
1.0 / 0.0	1	U/L

Assay Configuration: Calibration Page

Calib Mode	Factor	Interval (H)
Factor	1046.5	120
Blank/Calib Replicates	**Span**	**Span Abs Range**
3 / 0	**BLK** – 1	0.0 – 0.0

	Sample	S.Vol	DS.Vol	D.Vol	W.Vol	BLK Abs Range
BLK	Water	12.0	0.0	0	0	0.0 – 0.0
C1		2.0	0.0	0	0	**Cal Deviation**
C2		2.0	0.0	0	0	0.0

Assay Configuration: SmartWash Page

Rgt Probe

Reagent	Wash	Vol
—	—	—

Cuvette

Assay Name	Wash	Vol
—	—	—

Sample Probe

Wash
—

Refer to **Assay Configuration** in *Section 2* of the **AEROSET System Operations Manual** for information regarding assay parameters.

* User defined or instrument defined.

** The linear low value (L-Linear Range) is LOQ rounded up to the number of decimal places defined in the decimal places parameter field.