PSAP [rACPP/1338]

Concentrated and Prediluted Monoclonal Antibody
901-3263-060223

BIOCARE MEDICAL

Available Product Formats				
Format	Catalog Number	Description	Dilution	Diluent
Concentrate	ACI 3263 A, C	0.1, 1.0 mL	1:100	Renoir Red
Predilute	API 3263 AA	6.0 mL	Ready-to-use	N/A
ONCORE Pro	OPAI 3263 T60	60 tests	Ready-to-use	N/A
UltraLine – For BenchMark	AVI 3263 G	6.0 mL	Ready-to-use	N/A
Q Series– For Leica BOND-III	ALI 3263 G7	7.0 mL	Ready-to-use	N/A

Intended Use:
For In Vitro Diagnostic Use
PSAP [rACPP/1338] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of PSAP protein by immunohistochemistry (IHC) in formalin-fixed paraffin-embedded (FFPE) human tissues. The clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

Summary and Explanation:
Prostate-specific acid phosphatase (PSAP) is an enzyme produced in prostate epithelial cells. PSAP expression levels proportionally increase with prostate cancer progression (1). PSAP IHC staining is often used in conjunction with prostate specific antigen (PSA) staining to help distinguish poorly differentiated carcinomas. For instance, PSAP is commonly used to help differentiate prostate adenocarcinoma and urothelial carcinoma which may appear microscopically similar; prostate adenocarcinoma often stains with PSA and/or PSAP, while urothelial carcinoma does not (2). PSAP has a significantly higher correlation with the morphological characteristics of prostate cancer and can provide a more accurate predictive prognosis than other markers currently available. Since PSAP detection is a proportional measure of prostate cancer progression, it can also be used as an immunotherapy target for treatment of prostate cancer (1). Due to its prostate specificity, PSAP may also be a useful marker for excluding metastases from a prostatic primary, particularly in male breast cancer (3).

Principle of Procedure:
Antigen detection in tissues and cells is a multi-step immunohistochemical process. The initial step binds the primary antibody to its specific epitope. After labeling the antigen with a primary antibody, a one-, two- or three-step detection procedure can be employed. The one-step procedure will feature an enzyme-labeled polymer that binds to the primary antibody. A two-step procedure will feature a secondary antibody added to bind to the primary antibody. An enzyme-labeled polymer is then added to bind to the secondary antibody. The three-step detection procedure will feature a secondary antibody added to bind to the primary antibody followed by a linker antibody step for maximum binding. An enzyme-labeled polymer is then added to bind to the linker antibody. These detections of the bound antibodies are evidenced by a colorimetric reaction.

Source: Mouse monoclonal
Species Reactivity: Human, others not tested.
Clone: rACPP/1338
Isotype: IgG1, Kappa
Protein Concentration: Call for lot specific Ig concentration.
Epitope/Antigen: PSAP
Cellular Localization: Cytoplasmic
Positive Tissue Control: Normal prostate, prostate carcinoma

Known Applications:
Immunohistochemistry (formalin-fixed paraffin-embedded tissues)
Supplied As: Buffer with protein carrier and preservative

Storage and Stability:
Store at 2ºC to 8ºC. The product is stable to the expiration date printed on the label, when stored under these conditions. Do not use after expiration date. Diluted reagents should be used promptly; any remaining reagent should be stored at 2ºC to 8ºC.

Protocol Recommendations (intelliPATH FLX® and manual use):
Peroxide Block: Block for 5 minutes with Peroxidazed 1.
Pretreatment: Perform heat retrieval using Diva Decloaker. Refer to the Diva Decloaker product data sheet for specific instructions.
Protein Block (Optional): Incubate for 5-10 minutes at RT with Background Punisher.
Primary Antibody: Incubate for 30 minutes at RT.
Probe: Incubate for 10 minutes at RT with a secondary probe.
Polymer: Incubate for 10-20 minutes at RT with a tertiary polymer.
Chromogen: Incubate for 5 minutes at RT with Biocare's DAB – OR – Incubate for 5-7 minutes at RT with Warp Red.
Counterstain:
Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.
Technical Note:
This antibody, for intelliPATH FLX and manual use, has been standardized with MACH 4 detection system. Use TBS for washing steps.

Protocol Recommendations (ONCORE™ Pro Automated Slide Staining System):
OPAI3263 is intended for use with the ONCORE Pro. Refer to the User Manual for specific instructions for use. Protocol parameters in the Protocol Editor should be programmed as follows:
Protocol Name: PSAP
Protocol Template (Description): Ms HRP Template 1
Dewaxing (DS Buffer Option): DS2-50
Antigen Retrieval (AR Option): AR2, low pH; 101°C
Block Option: Buffer
Reagent Name, Time, Temp.: PSAP, 30 min., 25°C

Protocol Recommendations (Ventana BenchMark ULTRA):
AVI3263 is intended for use with the BenchMark ULTRA. Refer to the User Manual for specific instructions for use. Recommended protocol parameters are as follows:
Template/Detection: OptiView DAB IHC
Pretreatment Protocol: CC1 16 minutes
Peroxidase: Pre Primary Peroxidase Inhibitor
Primary Antibody: 16 minutes, 37°C

Protocol Recommendations (Q Series – For Leica BOND-III):
ALI3263 is intended for use with the Leica BOND-III. Refer to the User Manual for specific instructions for use. Recommended protocol parameters are as follows:
Protocol Name: IHC Protocol F
Detection: Bond Polymer Refine
HIER: 20 min with ER2
Peroxide Block: 5 min
Marker (Primary Antibody): 15 min
Post Primary: 8 min
Polymer: 8 min
Mixed DAB Refine: 10 min
Hematoxylin: 5 min

Biocare Medical
60 Berry Drive
Pacheco, CA 94553
USA

IVD CE

EC REP EMERGO EUROPE
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

Rev: 062117

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Performance Characteristics:
Sensitivity, specificity and cross-reactivity are summarized in Tables 1 and 2, respectively.

Limitations:
The optimum antibody dilution and protocols for a specific application can vary. These include, but are not limited to fixation, heat-retrieval method, incubation times, tissue section thickness and detection kit used. Due to the superior sensitivity of these unique reagents, the recommended incubation times and titers listed are not applicable to other detection systems, as results may vary. The data sheet recommendations and protocols are based on exclusive use of Biocare products. Ultimately, it is the responsibility of the investigator to determine optimal conditions.

Quality Control:
Refer to CLSI Quality Standards for Design and Implementation of Immunohistochemistry Assays; Approved Guideline-Second edition (I/LA28-A2) CLSI Wayne, PA USA (www.clsi.org). 2011

Precautions:
1. This antibody contains less than 0.1% sodium azide. Concentrations less than 0.1% are not reportable hazardous materials according to U.S. 29 CFR 1910.1200, OSHA Hazard communication and EC Directive 91/155/EC. Sodium azide (NaN_3) used as a preservative is toxic if ingested. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. Upon disposal, flush with large volumes of water to prevent azide build-up in plumbing. (Center for Disease Control, 1976, National Institute of Occupational Safety and Health, 1976) (4)
2. Specimens, before and after fixation, and all materials exposed to them should be handled as if capable of transmitting infection and disposed of with proper precautions. Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents and specimens. If reagents or specimens come into contact with sensitive areas, wash with copious amounts of water. (5)
3. Microbial contamination of reagents may result in an increase in nonspecific staining.
4. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change.
5. Do not use reagent after the expiration date printed on the vial.
6. The SDS is available upon request and is located at http://biocare.net.

Troubleshooting:
Follow the antibody specific protocol recommendations according to data sheet provided. If atypical results occur, contact Biocare's Technical Support at 1-800-542-2002.

References:

1. Kong HY, Byun J. Emerging roles of human prostatic acid phosphatase. Biomol Ther (Seoul). 2013;21(1):10-20.
2. Genega EM, Hutchinson B, Reuter VE, Gaudin PB. Immunophenotype of high-grade prostatic adenocarcinoma and urothelial carcinoma. Mod Pathol. 2000 Nov;13(11):1186-91.
3. Kidwai N, Gong Y, Sun X, et al. Expression of androgen receptor and prostate-specific antigen in male breast carcinoma. Breast Cancer Res. 2004;6(1): R18-R23.
4. Center for Disease Control Manual. Guide: Safety Management, NO. CDC-22, Atlanta, GA. April 30, 1976 "Decontamination of Laboratory Sink Drains to Remove Azide Salts."
5. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Fourth Edition CLSI document M29-A4 Wayne, PA 2014.

Table 1: Sensitivity and specificity were determined by testing formalin-fixed, paraffin-embedded diseased tissues.

Tissue	Positive Cases	Total Cases
Breast Cancer (IDC)	0	24
Colon Adenocarcinoma	0	40
Lung Adenocarcinoma	0	24
Lung Squamous Cell Carcinoma	0	24
Prostate Adenocarcinoma	47	48

Table 2: Tissue cross-reactivity was determined by testing formalin-fixed, paraffin-embedded normal tissues.

Tissue	Positive Cases	Total Cases
Cerebrum	0	2
Cerebellum	0	2
Adrenal	0	2
Ovary	0	2
Pancreas	0	3
Parathyroid	0	3
Pituitary	0	2
Testis	0	2
Thyroid	0	2
Breast	0	3
Spleen	0	3
Tonsil	0	3
Thymus	0	2
Bone Marrow	0	2
Lung	0	2
Heart	0	3
Esophagus	0	3
Stomach	0	3
Small Intestine	0	2
Colon	0	2
Liver	0	2
Salivary Gland	0	3
Kidney	0	3
Prostate	4	7
Uterus	0	3
Cervix	0	3
Skeletal Muscle	0	3
Skin	0	2
Peripheral Nerve	0	2
Lining Cells	0	2

Biocare Medical
60 Berry Drive
Pacheco, CA 94553
USA

IVD CE

EC REP EMERGO EUROPE
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands