Prostein

Concentrated and Prediluted Monoclonal Antibody
901-3163-102717

BIOCARE MEDICAL

Catalog Number:	**ACI 3163 A, B**	**API 3163 AA**
Description:	0.1, 0.5 ml, concentrated	6.0 ml, prediluted
Dilution:	1:100	Ready-to-use
Diluent:	Van Gogh Yellow	N/A

Intended Use:
For In Vitro Diagnostic Use
Prostein [10E3] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of prostein 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:
The prostein gene encodes a 553-amino acid type IIIa plasma membrane protein with a cleavable signal peptide and 11 transmembrane-spanning regions (1). IHC analysis has demonstrated that the Prostein antibody (also known as P501S) was expressed in the vast majority of normal and malignant prostatic tissues, regardless of grade and metastatic status. Prostein expression was not detected in thousands of representative normal and malignant non-prostatic tissue samples (2). Prostein has a perinuclear-like staining pattern, as expression is found in the Golgi complex of prostate cells (3). Compared to the PSA antibody, Prostein was positive in 99% of metastatic prostate adenocarcinomas while 97% of cases were positive for PSA. No tumor was negative for both markers (3). The International Society of Urological Pathology suggests the use of PSA, Prostein, NKX3.1, AMACR, GATA3 (or HMWCK and p63) and ERG antibodies for identification of prostatic adenocarcinoma in atypical glands and for differential diagnosis vs. urothelial carcinoma (4). Simultaneous stains with Prostein and PSA or NKX3.1 may greatly improve the detection rate and identification of a significant majority of prostatic metastases, especially poorly differentiated carcinomas of an unknown primary (3-5).

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 secondary antibody is added to bind to the primary antibody. An enzyme label is then added to bind to the secondary antibody; this detection of the bound antibody is evidenced by a colorimetric reaction.

Source: Mouse monoclonal
Species Reactivity: Human; others not tested
Clone: 10E3
Isotype: IgG2a/kappa
Total Protein Concentration: ~10 mg/ml. Call for lot specific Ig concentration.
Epitope/Antigen: Recombinant truncated prostein, containing amino acids 341-527
Cellular Localization: Cytoplasmic
Positive Tissue Control: Normal prostate or prostate cancer
Known Applications:
Immunohistochemistry (formalin-fixed paraffin-embedded tissues)
Supplied As: Buffer with protein carrier and preservative

Storage and Stability:
Store at 2ºC to 8ºC. Do not use after expiration date printed on vial. If reagents are stored under conditions other than those specified in the package insert, they must be verified by the user. Diluted reagents should be used promptly; any remaining reagent should be stored at 2ºC to 8ºC.

Protocol Recommendations:

Peroxide Block:
Block for 5 minutes with Biocare's Peroxidazed 1.
Pretreatment: Perform heat retrieval using Biocare's Diva Decloaker. Refer to the Diva Decloaker data sheet for specific instructions.
Protein Block (Optional): Incubate for 5-10 minutes at RT with Biocare's 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 Biocare's 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 has been standardized with Biocare's MACH 4 detection system. Use TBS buffer for washing steps.
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. The clinical interpretation of any positive or negative staining should be evaluated within the context of clinical presentation, morphology and other histopathological criteria by a qualified pathologist. The clinical interpretation of any positive or negative staining should be complemented by morphological studies using proper positive and negative internal and external controls as well as other diagnostic tests.
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) (6)

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Precautions Cont'd:
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. (7)
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. Xu J, *et al.* Identification and characterization of prostein, a novel prostate-specific protein. Cancer Res. 2001 Feb 15; 61(4):1563-8.
2. Kalos M, *et al.* Prostein expression is highly restricted to normal and malignant prostate tissues. Prostate. 2004 Aug 1; 60(3):246-56.
3. Sheridan T, *et al.* The role of P501S and PSA in the diagnosis of metastatic adenocarcinoma of the prostate. Am J Surg Pathol. 2007 Sep; 31(9):1351-5.
4. Epstein JI, *et al.* Best practices recommendations in the application of immunohistochemistry in the prostate: report from the International Society of Urologic Pathology consensus conference. Am J Surg Pathol. 2014 Aug; 38(8): e6-e19.
5. Gurel B, *et al.* NKX3.1 as a marker of prostatic origin in metastatic tumors. Am J Surg Pathol. 2010 Aug; 34(8):1097-105.
6. 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."
7. 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.

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