Prostate Specific Antigen (PSA)

Concentrated and Prediluted Rabbit Monoclonal Antibody
901-390-111519

BIOCARE MEDICAL

Catalog Number:	**CME 390 AK, CK**	**PME 390 AA**	**OAI 390 T60**	**VLTR 390 G20**
Description:	0.1, 1.0 mL, conc.	6.0 mL, RTU	60 tests, RTU	20 mL, RTU
Dilution:	1:100	Ready-to-use	Ready-to-use	Ready-to-use
Diluent:	Renoir Red	N/A	N/A	N/A

Intended Use:
For In Vitro Diagnostic Use
Prostate Specific Antigen (PSA) [EP109] is a rabbit monoclonal antibody that is intended for laboratory use in the qualitative identification of prostate specific antigen 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:
PSA is a chymotrypsin-like serine protease (kallikrein family) produced by the prostate epithelium. Studies have shown that PSA is used to confirm prostatic acinar cell origin in primary and metastatic carcinomas and to rule out non-prostatic carcinoma mimics. Prostate Specific Antigen (PSA) was tested on 167 cases of prostate adenocarcinoma for specificity and sensitivity and stained 98% of all prostate cancers (Table 1).

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-step or two-step detection procedure can be applied. A one-step procedure will feature an enzyme labeled polymer that binds the primary antibody. A two-step procedure will feature a linker antibody added to bind to the primary antibody. An enzyme-labeled polymer is then added to bind the linker antibody. These detections of the bound antibodies are evidenced by a colorimetric reaction.

Source: Rabbit monoclonal
Species Reactivity: Human, others not tested
Clone: EP109 (previously known as EP1588Y)
Isotype: IgG
Protein Concentration: Call for lot specific Ig concentration.
Epitope/Antigen: Prostate specific antigen
Cellular Localization: Cytoplasmic
Positive Tissue Control: Prostate or prostate carcinoma
Known Applications:
Immunohistochemistry (formalin-fixed paraffin-embedded tissues)
Supplied As: Buffer with protein carrier and preservative
Renoir Red Diluent (PD904)

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 (VALENT® Automated Slide Staining Platform):
VLTR390 is intended for use with the VALENT. Refer to the User Manual for specific instructions for use. Protocol parameters in the Protocol Manager should be programmed as follows:
- DAB Chromogen Staining Option:
Deparaffinization: Deparaffinize for 8 minutes with Val DePar.
Pretreatment: Perform heat retrieval at 98°C for 60 minutes using Val AR-Hi pH, 5X (use at 1X).
Peroxidase Block: Block for 5 minutes with Val Peroxidase Block.
Protein Block: Incubate for 10 minutes with Val Background Block.

Protocol Recommendations (VALENT Automated Slide Staining Platform) Cont'd:
Primary Antibody: Incubate for 20 minutes.
Secondary: N/A
Linker: Incubate for 10 minutes with Val Universal Linker.
Polymer: Incubate for 20 minutes with Val Universal Polymer.
Chromogen: Incubate for 5 minutes with Val DAB.
Counterstain: Counterstain for 5 minutes with Val Hematoxylin.
- Red Chromogen Staining Option:
Deparaffinization: Deparaffinize for 8 minutes with Val DePar.
Pretreatment: Perform heat retrieval at 98°C for 60 minutes using Val AR-Hi pH, 5X (use at 1X).
Protein Block: Incubate for 10 minutes with Val Background Block.
Primary Antibody: Incubate for 20 minutes.
Polymer: Incubate for 45 min with Val Rabbit AP Polymer.
Chromogen: Incubate for 15 min with Val Fast Red.
Counterstain: Counterstain for 5 minutes with Val Hematoxylin.

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 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: N/A
Polymer: Incubate for 30 minutes at RT with a secondary-conjugated 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™ Automated Slide Staining System):
OAI390 is intended for use with the ONCORE. Refer to the User Manual for specific instructions for use. Protocol parameters in the Protocol Editor should be programmed as follows:
Protocol Name: PSA Rb
Protocol Template (Description): Rb HRP Template 1
Dewaxing (DS Option): DS2
Antigen Retrieval (AR Option): AR2, low pH; 90°C
Reagent Name, Time, Temp.: PSA Rb, 30 min., 25°C

Limitations:
This antibody is to be used for paraffin-embedded tissue only and is not to be used in serum testing. 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.

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Limitations Cont'd:
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 in 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. Tazawa K, *et al.* Localization of prostate-specific antigen-like immunoreactivity in human salivary gland and salivary gland tumors. Pathol Int. 1999 Jun;49(6):500-5.
2. Siddiqui IA, *et al.* Inhibition of CWR22Rnu1 tumor growth and PSA secretion in athymic nude mice by green and black teas. Carcinogenesis. 2006 Apr; 27(4):833-9.
3. Ljung G, *et al.* Characterization of residual tumor cells following radical radiation therapy for prostatic adenocarcinoma; immunohistochemical expression prostatespecific antigen, prostatic acid phosphatase, and cytokeratin 8. Prostate. 1997 May 1;31(2):91-7.
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.

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Table 1:

Diagnosis	Total Cases	Positive	Negative	%+	%-
Prostate adenocarcinoma	167	163	4	98%	2%
Hyperplasia	20	20	0	100%	0%
Normal prostate	10	10	0	100%	0%
Chronic prostatitis	2	2	0	100%	0%
Stage III and IV	44	43	1	98%	2%
Gleason score 3-8	94	94	0	100%	0%
Gleason score 9-10	58	55	3	95%	5%
33 FDA normal tissue types	33	*1	32	3%	97%
Pancreatic cancers	21	0	21	0%	100%
Renal cell cancers	36	0	36	0%	100%
Colon cancers	126	0	126	0%	100%
Bladder cancers	90	0	90	0%	100%
Lung cancers	100	0	100	0%	100%
Liver cancers	16	0	16	0%	100%
Melanoma	13	0	13	0%	100%
Breast cancer	20	0	20	0%	100%
GIST	4	0	4	0%	100%
Leiomyosarcoma	4	0	4	0%	100%
Leiomyoma	4	0	4	0%	100%
Rhabdomyosarcoma	5	0	5	0%	100%
Seminoma	5	0	6	0%	100%
Stomach cancers	6	0	6	0%	100%

*Normal prostate

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