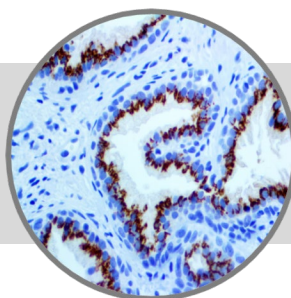


Prostein/P501S, RMAb

Clone: EP381**Rabbit Monoclonal**
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Inset: IHC of Prostein/P501S on a FFPE Prostate Tissue

Intended Use

For In Vitro Diagnostic Use.

This antibody is intended for use in Immunohistochemical applications on formalin-fixed paraffin-embedded tissues (FFPE), frozen tissue sections and cell preparations. Interpretation of results should be performed by a qualified medical professional.

Immunogen

Synthetic peptide corresponding to the N-terminus of human prostein.

Summary and Explanation

Prostein/ P501S also known as Solute Carrier Family 45 member 3 (SLC45A3) and prostate cancer-associated protein 6, is a protein that in humans is encoded by the SLC45A3 gene. Prostein is expressed in prostate-specific normal tissues and at a significantly lower level in prostate tumor cell lines, but not in any other normal or malignant tissue examined to date. Prostein is considered to be a good marker to demonstrate prostatic origin in metastatic prostate cancer.

Prostatic origin has been traditionally confirmed in most cases by immunohistochemistry for prostate-specific antigen (PSA) and prostate-specific acid phosphatase (PSAP). In a small subset of high-grade prostate carcinomas, both markers are negative and therefore are not helpful for confirming prostatic origin. Prostein/P501S stain yields a perinuclear cytoplasmic (Golgi) distribution even in poorly differentiated tumors and metastases. In one study, two distant metastases were negative for PSA but retained focal weak positivity for Prostein/P501S. Two other distant metastases were weakly PSA positive, but strongly Prostein positive. Metastases in the pelvic lymph nodes were positive for both markers in 53 cases and 1 lymph node metastasis. In summary, 67 of the 69 cases (97%) of metastatic prostate carcinomas were PSA positive, whereas 68 of the 69 cases showed at least focal weak reactivity for Prostein (99%). None of the tumors were negative for both markers. Therefore, the Immunohistochemistry for P501S is a sensitive and highly specific marker for identifying prostate metastases. The large majority of metastatic prostatic adenocarcinomas are Prostein/P501S positive (99%). A small subset of metastatic prostatic adenocarcinoma shows significant differences in staining intensity and extent for PSA and Prostein/P501S and, therefore, the combined use of these markers may result in increased sensitivity for detecting prostatic origin.

Antibody Type	Rabbit Monoclonal	Clone	EP381
Isotype	IgG	Reactivity	Paraffin, Frozen
Localization	Cytoplasmic	Control	Prostate, Prostatic Adenocarcinoma
Species Reactivity		Human	

Presentation

Prostein/P501S is a rabbit monoclonal antibody derived from cell culture supernatant that is concentrated, dialyzed, filter sterilized and diluted in buffer pH 7.5, containing BSA and sodium azide as a preservative.

Catalog No.	Antibody Type	Dilution	Volume/Qty
BSB 3162	Tinto Prediluted	Ready-to-Use	3.0 mL
BSB 3163	Tinto Prediluted	Ready-to-Use	7.0 mL
BSB 3164	Tinto Prediluted	Ready-to-Use	15.0 mL
BSB 3165	Concentrated	1:50 - 1:200	0.1 mL
BSB 3166	Concentrated	1:50 - 1:200	0.5 mL
BSB 3167	Concentrated	1:50 - 1:200	1.0 mL

Control Slides Available

Catalog No.	Quantity
BSB 3168	5 slides

Precautions

1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN₃) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as laboratory coat, goggles and gloves when handling reagents.
4. Dispose of unused solution with copious amount of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. For complete recommendations for handling biological specimens, please refer to the CDC document, "Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories" (see References in this document).

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Stability

This product is stable up to the expiration date on the product label. Do not use after expiration date listed on package label. Temperature fluctuations should be avoided. Store appropriately when not in use, and avoid prolonged exposure to room temperature conditions.

Specimen Preparation

Paraffin sections: The antibody can be used on formalin-fixed paraffin-embedded (FFPE) tissue sections. Ensure tissue undergoes appropriate fixation for best results. Pre-treatment of tissues with heat-induced epitope retrieval (HIER) is recommended using Bio SB ImmunoDNA Retriever with Citrate (BSB 0020-BSB 0023), ImmunoDNA Retriever with EDTA (BSB 0030-BSB 0033) or ImmunoDNA Digestor (BSB 0108-0112). See reverse side for complete protocol. Tissue should remain hydrated via use of Bio SB Immuno/DNA Washer solutions (BSB 0029 & BSB 0042).

Frozen sections and cell preparations: The antibody can be used for labeling acetone-fixed frozen sections and acetone-fixed cell preparations.

Staining Procedure

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively charged slides such as Bio SB Hydrophilic Plus Slides (BSB 7028).
2. Air dry for 2 hours at 58° C.
3. Deparaffinize, dehydrate and rehydrate tissues.
4. Subject tissues to heat induced epitope retrieval (HIER) using a suitable retrieval solution such as ImmunoDNA Retriever with Citrate (BSB 0020-BSB 0023) or EDTA (BSB 0030-BSB 0033).
5. Any of three heating methods may be used:

a. TintoRetriever Pressure Cooker or Equivalent

Place tissues/slides in a staining dish or coplin jar containing the ImmunoDNA Retriever with Citrate or EDTA, and place on trivet in the pressure cooker. Add 1-2 inches of distilled water to the pressure cooker and turn heat to high. Incubate for 15 minutes. Open and immediately transfer slides to room temperature.

b. TintoRetriever PT Module or Water Bath Method

Place tissues/slides in a pre-warmed staining dish or coplin jar containing the ImmunoDNA Retriever with Citrate or EDTA at 95°-99° C. Incubate for 30-60 minutes.

c. Conventional Steamer Method

Place tissues/slides in a pre-warmed staining dish or coplin jar containing the ImmunoDNA Retriever with Citrate or EDTA in a steamer, cover and steam for 30-60 minutes.

6. After heat treatment, transfer slides in ImmunoDNA Retriever with Citrate or EDTA to room temperature and let stand for 15-20 minutes.
7. For manual staining, perform antibody incubation at ambient temperature. For automated staining methods, perform antibody incubation according to instrument manufacturer's instructions.
8. Wash slides with ImmunoDNA washer or DI water.
9. Continue IHC staining protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical Protocol

Step	ImmunoDetector AP/HRP	PolyDetector AP/HRP	PolyDetector Plus HRP
Peroxidase/AP Blocker	5 min.	5 min.	5 min
Primary Antibody	30-60 min.	30-60 min.	30-60 min.
1st Step Detection	10 min.	30-45 min.	15 min.
2nd Step Detection	10 min.	Not Applicable	15 min.
Substrate-Chromogen	5-10 min.	5-10 min.	5-10 min.
Counterstain / Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.





Product Limitations

Due to inherent variability present in immunohistochemical procedures (including fixation time of tissues, dilution factor of antibody, retrieval method utilized and incubation time), optimal performance should be established through the use of positive and negative controls. Results should be interpreted by a qualified medical professional.

References

1. Entrez Gene: solute carrier family 45
2. Walker MG, et al. Prediction of gene function by genome-scale expression analysis: prostate cancer-associated genes. *Genome Res.* 1999; 9 (12): 1198-203.
3. Xu J, et al. Identification and characterization of prostatein, a novel prostate-specific protein. *Cancer Res.* 2001; 61 (4): 1563-8.
4. 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.
5. Yin M, et al. Diagnostic utility of p501s (prostein) in comparison to prostate specific antigen (PSA) for the detection of metastatic prostatic adenocarcinoma. *Diagn Pathol.* 2007; Oct 27;2:41
6. U.S. Department of Health and Human Services: Centers for Disease Control and Prevention. Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories. Supplement / Vol. 61, January 6, 2012.

Symbol Key / Légende des symboles/Erläuterung der Symbole

EC REP	EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands		Storage Temperature Limites de température Zulässiger Temperaturbereich		Manufacturer Fabricant Hersteller	REF	Catalog Number Référence du catalogue Bestellnummer
IVD	In Vitro Diagnostic Medical Device Dispositif médical de diagnostic in vitro In-Vitro-Diagnostikum		Read Instructions for Use Consulter les instructions d'utilisation Gebrauchsanweisung beachten		Expiration Date Utiliser jusque Verwendbar bis	LOT	Lot Number Code du lot Chargenbezeichnung

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