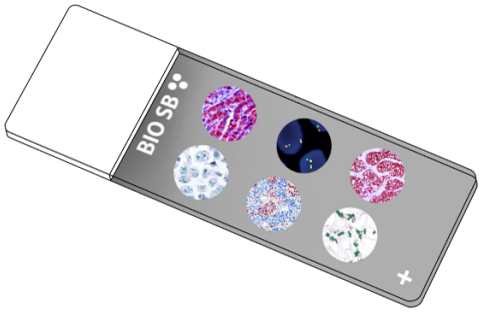
# Prostein/P501S Control Slides

CE IVD




**Intended Use**
For In Vitro Diagnostic Use.

**Summary and Explanation**
Prostein/ P501S also known as Solute Carrier Family 45 member 3 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 and prostate-specific acid phosphatase. 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.

**Presentation**
Five slides of Prostein/P501S positive tissues, each mounted on Hydrophilic Plus Slides, provided in a plastic mailer.

| *Catalog No.* | *Quantity* |
|---|---|
| BSB-9355-CS | 5 slides |
| BSB 3168 | 5 slides |

**Storage** Store at 20-25°C

**Precautions**
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. 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).

**Stability**
**This product is stable up to the expiration date on the product label.**
Do not use after expiration date listed on package label.

**IHC Protocol**
1. 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).
2. 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.
3. After heat treatment, transfer slides in ImmunoDNA Retriever with Citrate or EDTA to room temperature and let stand for 15-20 minutes.
4. For manual staining, perform antibody incubation at ambient temperature. For automated staining methods, perform antibody incubation according to instrument manufacturer's instructions.
5. Wash slides with ImmunoDNA washer or DI water.
6. 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 |

**Abbreviated IF Protocol**

| Step | Incubation Time |
|---|---|
| Rinse slides in IF wash buffer | 5 minutes |
| Drain and wipe excess IF wash buffer off slide | |
| Conduct remaining steps in the dark | |
| Apply Antibody | 30-60 minutes |
| Rinse with 3 changes of IF wash buffer | 3x15 minutes each |
| Coverslip with IF mounting medium | |

**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 prostein, 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. https://www.cdc.gov/mmwr/pdf/other/su6101.pdf


**Symbol Key / Légende des symboles/Erläuterung der Symbole**

| | | | |
|---|---|---|---|
| EC REP<br>QAdvis EAR AB<br>Ideon Science Park<br>Scheelevägen 17<br>SE-223 70 Lund, Sweden | Storage Temperature<br>Limites de température<br>Zulässiger Temperaturbereich | Manufacturer<br>Fabricant<br>Hersteller | REF<br>Catalog Number<br>Référence du catalogue<br>Bestellnummer |
| IVD<br>In Vitro Diagnostic Medical Device<br>Dispositif médical de diagnostic in vitro<br>In-Vitro-Diagnostikum | Read Instructions for Use<br>Consulter les instructions d'utilisation<br>Gebrauchsanweisung beachten | Expiration Date<br>Utiliser jusque<br>Verwendbar bis | LOT<br>Lot Number<br>Code du lot<br>Chargenbezeichnung |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