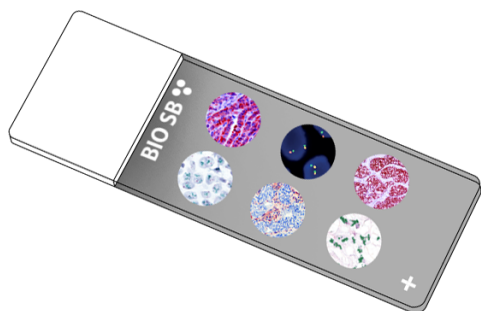


EpCAM/Epithelial Specific Antigen Control Slides



Intended Use

For In Vitro Diagnostic Use.

Summary and Explanation

Epithelial Cell Adhesion Molecule or Epithelial Specific Antigen is a 40kD cell surface antigen that is broadly distributed in epithelial cells and displays a highly conserved expression in carcinomas. These glycoproteins are located on the cell membrane surface and in the cytoplasm of virtually all epithelial cells, with the exception of most squamous epithelia, hepatocytes, renal proximal tubular cells, gastric parietal cells and myoepithelial cells. However, focal positivity may be seen in the basal layer of squamous cell epithelium of endoderm (e.g., palatine tonsils) and mesoderm (e.g., uterine cervix).

EpCAM expression has been reported to be a possible marker of early malignancy, with expression being increased in tumor cells, and de novo expression being seen in dysplastic squamous epithelium. Epithelial specific antigen has been known to play an important role as a tumor-cell marker in lymph nodes from patients with esophageal carcinoma. EpCAM can be used to distinguish among Basal Cell, Basosquamous Carcinomas and Squamous Cell Carcinomas of the skin.

Presentation

Five slides of EpCAM/Epithelial Specific Antigen positive tissues, each mounted on Hydrophilic Plus Slides, provided in a plastic mailer.

| <i>Catalog No.</i> | <i>Quantity</i> |
|--------------------|-----------------|
| BSB-9169-CS | 5 slides |
| BSB 6281 | 5 slides |
| BSB 6729 | 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. Beer TW, et al. Histopathology. 2000;37:218-223
2. Carella R, et al. Am J Surg Pathol. 2001;25:43-50
3. Hosch S, et al. Cancer Res. 2000; 60:6836-6840
4. Latza U, et al. J Clin Pathol. 1990;43:213-219
5. 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 QAdvis EAR AB Ideon Science Park Scheelevägen 17 SE-223 70 Lund, Sweden |  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 jusqu'à Verwendbar bis | LOT Lot Number Code du lot Chargenbezeichnung |