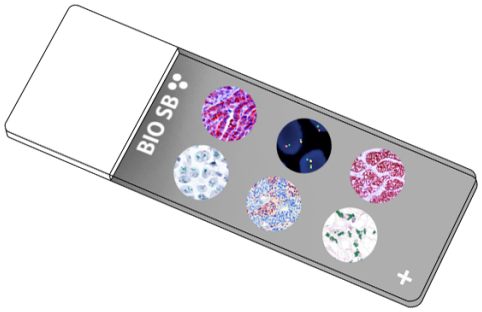
Mesothelial Cell Control Slides

CE IVD



Intended Use
For In Vitro Diagnostic Use.

Summary and Explanation
Mesothelial Cell HBME-1 has shown to label mesothelial cells, both benign and malignant (malignant mesothelioma) and thus has been used in distinguishing mesothelioma from adenocarcinomas of various origins. HBME-1 has also been used to distinguish Thyroid carcinomas (both Follicular and Papillary) from benign thyroid lesions.

Mesothelial Cell HBME-1 and MOC-31 have been shown to have a diagnostic efficiency for the distinction between carcinoma and mesothelioma in pleura. HBME-1 staining may be useful for differentiating papillary carcinomas from follicular carcinomas; in papillary lesions it tends to be positive. Several immunohistochemical markers have been used to aid in the diagnosis of follicular-derived lesions of the thyroid. HBME-1, ERK, and p16 were found to be more specific for malignancy, whereas CK19 and GAL-3 stained benign lesions with a higher frequency and were not specific for malignant FDLT.

A study of thyroid nodules with cytological atypia with strong/diffuse positivity for both HBME-1 and Galectin-3, two well recognized markers of papillary thyroid carcinomas, represent a starting phenotypic change towards PTC, for which a benign or borderline counterpart has not yet been defined. The expression of HBME-1 and Galectin-3 in some thyroid nodules is related to the presence of cytological atypia suggestive but not diagnostic of PTC. The phenotypic similarity between this subset of thyroid nodules with cytological atypia and PTC is also confirmed by data according to which Galectin-3 and HBME-1 have been found to be highly sensitive for PTC.

Presentation
Five slides of Mesothelial Cell positive tissues, each mounted on Hydrophilic Plus Slides, provided in a plastic mailer.

Catalog No.	*Quantity*
BSB-9277-CS	5 slides
BSB 3461	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 the 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. González-Lois C, et al. Combined use of novel epithelial (MOC-31) and mesothelial (HBME-1) immunohistochemical markers for optimal first line diagnostic distinction between mesothelioma and metastatic carcinoma in pleura. Histopathology. 2001 Jun;38(6):528-34.
2. Barroeta JE, et al. Diagnostic value of differential expression of CK19, Galectin-3, HBME-1, ERK, RET, and p16 in benign and malignant follicular-derived lesions of the thyroid: an immunohistochemical tissue microarray analysis. Endocr Pathol. 2006 Fall;17(3):225-34.
3. Papotti M, et al. Galectin-3 and HBME-1 expression in well-differentiated thyroid tumors with follicular architecture of uncertain malignant potential. Mod. Pathol. 2005; 18 (4): 541–46.
4. 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 jusque / Verwendbar bis	LOT — Lot Number / Code du lot / Chargenbezeichnung

Bio SB
BIOSCIENCE FOR THE WORLD
5385 Hollister Avenue, Bldg. 8, Ste. 108, Santa Barbara, CA 93111, USA
Tel. (805) 692-2768 | Tel. (800) 561-1145 | Fax. (805) 692-2769
E-mail: sales@biosb.com | Website: www.biosb.com