HBME-1

Prediluted Monoclonal Antibody

Control Number: 901-3177-090817

Catalog Number: **API 3177 AA**

Description: 6.0 ml, prediluted

Dilution: Ready-to-use

Diluent: N/A

Intended Use:

For In Vitro Diagnostic Use

HBME-1 is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of mesothelial cells 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:

The monoclonal antibody against HBME-1 targets an unknown antigen of mesothelial microvilli (1). HBME-1 is abnormally expressed in thyroid cancer, showing cytoplasmic location with membrane accentuation (2-5). Anti-HBME-1 has been most extensively investigated as an immunochemical (IHC) marker in thyroid cancer. It has a sensitivity of 78.3% and specificity of 85.4% in 10 studies using preoperative fine needle aspirate (FNA) specimens (3,5). Similar sensitivity of 77% and specificity of 83% have been reported in meta-analysis of 21 IHC studies on formalin-fixed paraffin-embedded tissue sections (4). Most papillary thyroid carcinomas (PTC) show diffuse positive staining for HBME-1 (55%–100%; mean, 88%) (1). One study has reported a sensitivity of 70% and 45% for the classical and follicular variant of PTC, respectively (1). HBME-1 detection in thyroid follicular carcinomas in different studies has varied between 50% and 100% (mean, 75%) (1). A small series of an oncocytic variant of papillary and follicular carcinoma have demonstrated positive HBME-1 staining in 13% to 66% of cases (1). Poorly differentiated and anaplastic carcinomas also often express HBME-1 (67%–91% and 0%–50%, respectively) (1). HBME-1 is strongly expressed in mesothelium, bronchial epithelium, endocervical epithelium and cartilage; variably positive or focal positive in alveolar lining cells of the lung, myoepithelium of breast ducts, endometrial glands with luminal (apical) staining pattern and scattered histiocytes in lymphoid tissue. HBME-1 is negative in epithelium of GI tract, squamous epithelium, liver, kidney, testis, thyroid, placenta, connective tissue, muscle (skeletal and smooth), skin epidermis and dermis and lymphoid tissue (1-5).

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 secondary antibody is added to bind to the primary antibody. An enzyme label is then added to bind to the secondary antibody; this detection of the bound antibody is evidenced by a colorimetric reaction.

Source: Mouse monoclonal

Species Reactivity: Human; others not tested

Clone: HBME-1

Isotype: IgM/kappa

Total Protein Concentration: ~10 mg/ml. Call for lot specific Ig concentration.

Epitope/Antigen: Mesothelial cells

Cellular Localization: Cytoplasmic/cell membrane

Positive Tissue Control: Papillary thyroid carcinoma

Known Applications:

Immunohistochemistry (formalin-fixed paraffin-embedded tissues)

Supplied As: Buffer with protein carrier and preservative

Storage and Stability:

Store at 2ºC to 8ºC. Do not use after expiration date printed on vial. If reagents are stored under conditions other than those specified in the package insert, they must be verified by the user.

Protocol Recommendations:

Peroxide Block: Block for 5 minutes with Biocare's Peroxidazed 1.

Pretreatment: Perform heat retrieval using Biocare's Diva Decloaker. Refer to the Diva Decloaker data sheet for specific instructions.

Protein Block (Optional): Incubate for 5-10 minutes at RT with Biocare's Background Punisher.

Primary Antibody: Incubate for 60 minutes at RT.

Probe: Incubate for 10 minutes at RT with a secondary probe.

Polymer: Incubate for 10-20 minutes at RT with a tertiary polymer.

Chromogen:

Incubate for 5 minutes at RT with Biocare's DAB – OR – Incubate for 5-7 minutes at RT with Biocare's 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 has been standardized with Biocare's MACH 4 detection system. Use TBS buffer for washing steps.

Limitations:

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. 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. The clinical interpretation of any positive or negative staining should be evaluated within the context of clinical presentation, morphology and other histopathological criteria by a qualified pathologist. The clinical interpretation of any positive or negative staining should be complemented by morphological studies using proper positive and negative internal and external controls as well as other diagnostic tests.

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) (6)
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 into contact with sensitive areas, wash with copious amounts of water. (7)
3. Microbial contamination of reagents may result in an increase in nonspecific staining.

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Precautions Cont'd:

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.

References:

1. Fischer S, Asa SL. Application of immunohistochemistry to thyroid carcinoma. Arch Pathol Lab Med. 2008; 132:359-72.
2. Sack MJ, *et al*. HBME-1 immunostaining in thyroid fine-needle aspirations: a useful marker in the diagnosis of carcinoma. Mod Pathol. 1997; 10:668–74.
3. Rodrigues HGC, *et al*. Use of molecular markers in samples obtained from preoperative aspiration of thyroid. Endocr J. 2012; 59:417–24.
4. de Matos LL, *et al*. Expression of CK-19, galectin-3 and HBME-1 in the differentiation of thyroid lesions: systematic review and diagnostic meta-analysis. Diagn Pathol. 2012; 7:97.
5. Zhang L, *et al*. A pilot study of galectin-3, HBME-1, and p27 triple immunostaining pattern for diagnosis of indeterminate thyroid nodules in cytology with the correlation to histology. Appl Immunohistochem Mol Morphol. 2015; 23:481–90.
6. 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."
7. 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.

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.

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