Ber-EP4 + BG8

Prediluted Antibody Cocktail

Control Number: 901-3112-092017

Catalog Number: **API 3112 AA**
Description: 6.0 ml, prediluted
Dilution: Ready-to-use
Diluent: N/A

Intended Use:
For In Vitro Diagnostic Use
Ber-EP4 + BG8 is a mouse monoclonal antibody cocktail that is intended for laboratory use in the qualitative identification of the cell surface glycoprotein known as Epithelial Antigen and BG8 Lewis Y antigen 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:

Ber-EP4, an anti-EpCAM antibody, detects epithelial glycoproteins of 34 and 39 kDa on the cell membrane surface and in the cytoplasm of epithelial cells. Ber-EP4 labels epithelial tissues but does not label mesothelial cells (1). Ber-EP4 can assist in differentiating epithelial pleural mesotheliomas from adenocarcinomas (1,2). One study observed 100% reactivity for lung adenocarcinomas with Ber-EP4 (2). In another study, Ber-EP4 appears to stain all adenocarcinomas except breast and kidney (1).

BG8 (Blood Group Lewis Y) [F3] detects the Lewis Y antigen. One study showed that BG8 was negative for almost all epithelial malignant mesotheliomas (91% sensitivity) (3). When trying to distinguish epithelioid mesothelioma from adenocarcinoma, BG8 appears to be very sensitive for breast carcinoma (96%) (4). A panel of Ber-EP4, BG8 and MOC-31 stained 100% of lung carcinomas (4). Studies have shown that specificity of BG8 and Ber-EP4 for adenocarcinoma was 98% and 95%, respectively (4).

A cocktail of Ber-EP4 and BG8 may be a useful tool to distinguish adenocarcinoma from mesothelioma.

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.

Reagent Provided:
Ber-EP4 + BG8 is provided as a prediluted antibody cocktail of anti-Ber-EP4 and anti-BG8 antibodies in buffer with carrier protein and preservative.

Antibody	anti-Ber-EP4	anti-BG8
Clone	Ber-EP4	F3
Source	Mouse monoclonal	Mouse monoclonal
Isotype	IgG1	IgM
Epitope/ Antigen	Epithelial Antigen	BG8 Lewis Y
Cellular Localization	Cytoplasmic, membranous	Cytoplasmic, membranous

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.

Known Applications:
Immunohistochemistry (formalin-fixed paraffin-embedded tissues)
Species Reactivity: Human; others not tested
Positive Tissue Control: Colon cancer, lung adenocarcinoma

Protocol Recommendations:

Peroxide Block: Block for 5 minutes with Biocare's Peroxidazed 1.
Pretreatment Solution (recommended): N/A
Pretreatment Protocol: N/A
Digestion Method:
Digest with Pepsin enzyme for 20 minutes at RT.
Protein Block (Optional): Incubate for 5-10 minutes at RT with Biocare's Background Punisher.
Primary Antibody: Incubate for 30 minutes at RT.
Probe: Incubate for 10 minutes at RT with a secondary probe.
Polymer: Incubate for 10 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 Notes:

This antibody has been standardized with Biocare's MACH 4 detection system. It can also be used on an automated staining system and with other Biocare polymer detection kits. 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) (5)
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. (6)
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/.

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.

References:

1. Sheibani K, *et al.* Ber-EP4 antibody as a discriminant in the differential diagnosis of malignant mesothelioma versus adenocarcinoma. Am J Surg Pathol. 1991 Aug; 15 (8):779-84.
2. Ordóñez NG. Value of the Ber-EP4 antibody in differentiating epithelial pleural mesothelioma from adenocarcinoma. The M.D. Anderson experience and a critical review of the literature. Am J Clin Pathol. 1998 Jan; 109(1):85-9.
3. Kao SC, *et al.* Validation of a minimal panel of antibodies for the diagnosis of malignant pleural mesothelioma. Pathology. 2011 Jun;43(4):313-7.
4. Yaziji H, *et al.* Evaluation of 12 antibodies for distinguishing epithelioid mesothelioma from adenocarcinoma: identification of a three-antibody immunohistochemical panel with maximal sensitivity and specificity. Mod Pathol. 2006 Apr; 19(4):514-23.
5. 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."
6. 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.

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