Cytokeratin [AE1] LMW

Prediluted Monoclonal Antibody
901-081-020818

BIOCARE MEDICAL

Catalog Number:	**PM 081 AA**
Description:	6.0 ml, prediluted
Dilution:	Ready-to-use
Diluent:	N/A

Intended Use:
For In Vitro Diagnostic Use
Cytokeratin [AE1] LMW is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of low molecular weight cytokeratin proteins (CK 10, 14, 15, 16, 19) 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:
Monoclonal antibody AE1 recognizes the acidic (Type 1) subfamilies of cytokeratins. The acidic cytokeratins have molecular weights of 56.5, 50, 50, 48 and 40 kDa (10, 14, 15, 16, and 19). Studies have shown AE1 to be useful for marking tumors for squamous and adenocarcinoma of the lung, liver carcinoma, breast cancer, and esophageal cancer (1-2). AE1 shows a broad species reactivity.

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, mouse and rat
Clone: AE1
Isotype: IgG1
Total Protein Concentration: ~10 mg/ml. Call for lot specific Ig concentration.
Epitope/Antigen: CK Type I (LMW)
Cellular Localization: Cytoplasmic
Positive Tissue Control: Skin or adenocarcinoma
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 Solution (recommended): Diva or Reveal, or Pepsin digestion
Pretreatment Protocol:
Heat Retrieval Method:
Perform heat retrieval using Biocare's Diva or Reveal Decloaker. Refer to the Diva or Reveal Decloaker product data sheet for specific instructions.
Digestion Method:
Digest with Pepsin enzyme for 5 minutes at 37°C –or- for 15 minutes at RT.
Protein Block (Optional): Incubate for 5-10 minutes at RT with Biocare's Background Punisher.

Protocol Recommendations Cont'd:
Primary Antibody: Incubate for 30 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 Notes:
1. With cytokeratin markers, heat retrieval may provide a higher sensitivity assay; whereas, enzyme digestion may produce greater specificity. Users should validate the pretreatment method for their specific application.
2. 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) (3)
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 in contact with sensitive areas, wash with copious amounts of water. (4)
3. Microbial contamination of reagents may result in an increase in nonspecific staining.
4. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change.

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Precautions Cont'd:

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. Bunton TE. The immunocytochemistry of cytokeratin in fish tissues. Vet Pathol. 1993, Sep;30(5):418-25.
2. Sandusky GE, *et al.* Immunocytochemical study of tissues from clinically normal dogs and neoplasms, using keratin monoclonal antibodies. Am J Vet Res. 1991 Apr;52(4):613-18.
3. 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."
4. 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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