Pan Cytokeratin [AE1/AE3]

ISO 9001&13485 CERTIFIED

BIOCARE

Prediluted Cocktail Antibody Control Number: 901-011VP-021916

VP Echelon[™] Series

Catalog Number:	VP 011 G, G25
Description:	6.0, 25.0 ml, prediluted
Dilution:	Ready-to-use

Intended Use:

For In Vitro Diagnostic Use

Pan Cytokeratin [AE1/AE3] is a mouse monoclonal antibody cocktail that is intended for laboratory use in the qualitative identification of a broad spectrum of acidic and basic cytokeratin proteins by immunohistochemistry (IHC) in formalin-fixed paraffinembedded (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:

AE1/AE3 recognizes the acidic and basic (Type I and II) subfamilies of cytokeratins. The cocktail of these two antibodies can be used to detect most human epithelia. The acidic cytokeratins have molecular weights of 56.5, 55, 51, 50, 50, 48 46, 45, and 40 kDa. The basic cytokeratins have molecular weights of 65-67, 64, 59, 58, 56 and 52 kDa. This pan cytokeratin antibody has proved useful as a screener for the majority of human carcinomas.

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, an enzyme labeled polymer is added to bind to the primary antibody. The detection of the bound antibody is evidenced by a colorimetric reaction

Source: Mouse monoclonal

Species Reactivity: Human, mouse and rat

Clone: AE1/AE3

Isotype: IgG1

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

Epitope/Antigen: AE1/AE3

Cellular Localization: Cytoplasmic

Positive 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 2°C to 8°C. 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:

Using ultraVIEW Detection Kit

Pretreatment Solution (recommended): CC1

Pretreatment Protocol: Standard

Primary Antibody: Incubate for 32 minutes at 37°C.

V-Blocker is recommended to be applied prior to any detection system.

ultraBlock (BRI4001): Incubate for 4 minutes (with appropriate Option # registered by user)

Technical Note:

 Biocare's VP Echelon Series of predilutes have been developed for use with Ventana® Medical Systems, BenchMark® XT Immunohistochemistry Staining System in combination with Ventana® Detection Kits and Ventana® Prep Kit Dispensers.
Application of V-Blocker prior to any detection system is highly recommended for background reduction.

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 (NaN₃) 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.

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.

Biocare Medical 4040 Pike Lane Concord, CA 94520 USA



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References:

1. Bunton TE. The immunocytochemistry of cytokeratin in fish tissues. Vet Pathol. 1993 Sep; 30(5):418-25.

2. Sorensen SC, *et al.* Structural distinctions among human breast epithelial cells revealed by the monoclonal antikeratin antibodies AEI and AE3. J Pathol. 1987 Oct; 153(2):151-62.

3. Pinkus GS, Etheridge CL, O'Connor EM. Are keratin proteins a better tumor marker than epithelial membrane antigen? A comparative immunohistochemical study of various paraffin-embedded neoplasms using monoclonal and polyclonal antibodies. Am J Clin Pathol. 1986 Mar; 85(3):269-77.

4. Pinkus GS, *et al.* Optimal immunoreactivity of keratin proteins in formalin-fixed, paraffin-embedded tissue requires preliminary trypsinization. An immunoperoxidase study of various tumours using polyclonal and monoclonal antibodies. J Histochem Cytochem. 1985 May; 33(5):465-73.

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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