BIOCARE MEDICAL

ISO 9001&13485 CERTIFIED

Pan Cytokeratin [Lu-5]

Prediluted Monoclonal Antibody

Control Number: 901-043VP-111615

VP Echelon™ Series

Catalog Number: **VP 043 G**

Description: 6.0 ml, prediluted

Dilution: Ready-to-use

Intended Use:

For In Vitro Diagnostic Use

Pan Cytokeratin [Lu-5] is mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of most cytokeratin proteins of both the acidic (type I) and basic (type II) subfamilies 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:

Lu-5 is useful in differentiating epithelial and mesothelial cells from mesenchymal cells in normal and tumor tissues. It serves as a first-order pan cytokeratin antibody for both acidic (type I) and basic type (basic type II) cytokeratin subfamilies of all vertebrates tested so far. Lu-5 stains an intracytoplasmic, formaldehyde-resistant epitope on the surface of cytokeratin filaments. Lu-5 has been shown to be superior to AEI/AE3.

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: Lu-5

Isotype: IgG1

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

Epitope/Antigen: Pan Cytokeratin

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 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:

Using ***ultra*VIEW Detection Kit**

Pretreatment Solution (recommended): N/A

Pretreatment Protocol: N/A

Digestion Method: Digest with Ventana's Protease #1. Incubate for 16 minutes.

Primary Antibody: Incubate for 32 minutes at 37ºC.

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.

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 in contact with sensitive areas, wash with copious amounts of water. (7)
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.

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References:

1. Schroder S, Wodzynski A, Padberg B. Cytokeratin expression of benign and malignant epithelial thyroid gland tumors. An immunohistologic study of 154 neoplasms using 8 different monoclonal cytokeratin antibodies. Pathologe. 1996 Nov;17(6):425-32.
2. Mullhaupt B, *et al.* The common pattern of cytokeratin alteration in alcoholic and cholestatic liver disease is different from that of hepatic liver damage. A study with the panepithelial monoclonal antibody lu-5. J Hepatol. 1993 Aug;19(1):23-35.
3. Moch H, *et al.* Diagnostic tools for differentiating between pleural mesothelioma and lung adenocarcinoma in paraffin-embedded tissue. Part I: Immunohistochemical findings. Virchows Arch A Pathol Anat Histopathol. 1993;423(1):19-27.
4. Goddard MJ, Wilson B, Grant JW. Comparison of commercially available cytokeratin antibodies in normal and neoplastic adult epithelial and non-epithelial tissues. J Clin Pathol. 1991 Aug;44(8):660-3.
5. Forster C, Bassler R. Comparative immunohistochemical studies of the histopathology of the breast using monoclonal antibodies Lu-5 and b-12. Pathologe. 1991 Mar;12(2):60-5.
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

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