BIOCARE MEDICAL

ISO 9001&13485 CERTIFIED

CD3 T-Cell (M)

Prediluted Monoclonal Antibody

Control Number: 901-110VP-090314

VP Echelon™ Series

Catalog Number: **VP 110 G**

Description: 6.0 ml, prediluted

Dilution: Ready-to-use

Intended Use:
For In Vitro Diagnostic Use

Summary and Explanation:
Monoclonal antibody to human CD3, when used in conjunction with other antibodies, is regarded as a reliable pan T-cell antibody used in the immunophenotyping of lymphomas in paraffin sections. Most T-cell lymphomas show positivity for CD3. Notable exceptions include some of the more aggressive large T-cell lymphomas and anaplastic large cell (Ki-1, CD30) lymphomas, which may not express detectable antigen. CD3 immunoreactivity has also been reported in a minority of Reed-Sternberg cells of Hodgkin's disease and in some histiocytic tumors. CD3 expression of hemapoietic cells of the lymphoid, myeloid, and erythroid lineages in the human fetal and embryonic liver is rare. In a study of 50 archived T-cell lymphomas UCHL-1 (a monoclonal antibody to CD45RO) showed reactivity with 94% of cases, but lacked absolute specificity for T-cells, especially in high-grade lymphomas[2]. CD3 showed reactivity with 80% of neoplastic cells, but with a higher specificity. Used in conjunction, UCHL-1 and monoclonal CD3 identified the majority of T-cell lymphomas in paraffin sections.

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: PS1

Isotype: IgG_{2a}

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

Epitope/Antigen: CD3

Cellular Localization: Predominantly cell membrane. Some cytoplasmic.

Positive Control: Tonsil or T-cell lymphoma

Normal Tissue: Tonsil

Abnormal Tissue: T-cell lymphoma

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 ***i*VIEW™ Detection Kit**

Pretreatment Solution (recommended): CCI

Pretreatment Protocol: Standard

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 listed are not applicable to other detection systems, as results may vary. Ultimately, it is the responsibility of the investigator to determine optimal conditions. These products are tools that can be used for interpretation of morphological findings in conjunction with other diagnostic tests and pertinent clinical data by a qualified pathologist.

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:
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)
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. Microbial contamination of reagents may result in an increase in nonspecific staining. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change. The MSDS is available upon request and is located at http://biocare.net/support/msds/.

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. Steward M, Bishop R, Piggott NH, Milton ID, Angus B, Horne CH. Production and characterization of a new monoclonal antibody effective in recognizing the CD3 T-cell associated antigen in formalin-fixed embedded issue. Histopathology. 1997 Jan; 30 (1):16-22.

2. Cabecadas JM, Isaacson PG. Phenotyping of T-cell lymphomas in paraffin sections--which antibodies? Histopathology. 1991 Nov; 19(5):419-24.

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-Third Edition CLSI document M29-A3 Wayne, PA 2005

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