CD4 [4B12]
Concentrated and Prediluted Monoclonal Antibody
901-3148-011720

Intended Use:
For In Vitro Diagnostic Use
CD4 [4B12] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of CD4 protein 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:
CD4 is a transmembrane glycoprotein, expressed on normal thymocytes, T-helper cells, the majority of mature peripheral T cells, and a subset of suppressor or cytotoxic T cells (1). Like many cell surface receptors/markers, CD4 is a member of the immunoglobulin superfamily. CD4 is expressed in the majority of T-cell lymphomas, including mycosis fungoides (2). CD4 has been used in lymphoma panels including mycosis fungoides (3). A panel consisting of CD4(+), CD2(-) and CD56(+) antibodies was also used to help identify agranular natural killer cell lymphoma of the skin (4). A CD4 assessment may be useful in HIV-infected individuals, as HIV infection depletes intestinal CD4(+) T cells and has a strong association with the level of systemic CD4(+) T cell activation (5). Tumor infiltrating CD4 T cells may also be a prognostic factor for the strategy of early antitumor immunity (6).

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 one-, two- or three-step detection procedure can be employed. The one-step procedure will feature an enzyme-labeled polymer that binds to the primary antibody. A two-step procedure will feature a secondary antibody added to bind to the primary antibody. An enzyme-labeled polymer is then added to bind to the secondary antibody. The three-step detection procedure will feature a secondary antibody added to bind to the primary antibody followed by a linker antibody step for maximum binding. An enzyme-labeled polymer is then added to bind to the linker antibody. These detections of the bound antibodies are evidenced by a colorimetric reaction.

Source: Mouse monoclonal
Species Reactivity: Human; others not tested
Clone: 4B12
Isotype: IgG1/kappa

Protocol Recommendations (VALENT® Automated Slide Staining Platform):
VLTM3148 is intended for use with the VALENT. Refer to the User Manual for specific instructions for use. Protocol parameters in the Protocol Manager should be programmed as follows:
Deparaffinization: Deparaffinize for 8 minutes with Val DePar.

Protocol Recommendations (intelliPATH FLX® and manual use):
Peroxidase Block: Block for 5 minutes with Peroxidased 1.

Technical Note:
This antibody, for intelliPATH FLX and manual use, has been standardized with MACH 4 detection system. Use TBS 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 times 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.

Quality Control:
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
Precautions Cont’d:
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) (7)
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. (8)
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.

References: