CD3 T-Cell (M) 
Prediluted Mouse Monoclonal Antibody
Control Number: 901-110IP-071913

Catalog Number: IP 110 G10
Description: 10 ml, predilute

Intended Use:
For In Vitro Diagnostic Use
CD3 T-Cell (M) [PS1] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of CD3 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:
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 hematopoetic 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. CD3 showed reactivity with 80% of neoplastic cells, but with a higher specificity (1). When used in conjunction, UCHL-1 and monoclonal CD3 identified the majority of T-cell lymphomas in paraffin sections (2).

Tonsil stained with CD3 antibody.

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: IgG2a
Epitope/Antigen: CD3
Total Protein Concentration: ~10 mg/ml. Call for lot specific Ig concentration.
Positive Control: Tonsil or 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.

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) (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.
5. Do not use reagent after the expiration date printed on the vial.
6. The MSDS is available upon request and is located at http://biocare.net/support/msds/.

Protocol Recommendations:
Pre-treatment Solution (recommended): Borg or Reveal
Pre-treatment Protocol:
Heat Retrieval Method:
Retrieve sections under pressure using Biocare’s Decloaking Chamber, followed by a wash in distilled water; alternatively, steam tissue sections for 45-60 minutes. Allow solution to cool for 10 minutes then wash in distilled water.

 Peroxide Block: Block for 5 minutes at RT.
 Protein Block (Optional): Incubate for 5-10 minutes at RT.
 Primary Antibody: Incubate for 30-45 minutes at RT.
 Secondary: Incubate for 10 minutes at RT.
 Tertiary: Incubate for 10-20 minutes at RT.
 Chromogen: Incubate for 5 minutes with DAB at RT.
 Counterstain: 1. Rinse with deionized water.
 2. Incubate for 5 minutes with automated Hematoxylin.
 3. Rinse with TBS Buffer for 1 minute followed by a rinse with deionized water.

Staining Procedure:
Biocare protocols have been standardized using in-house antibodies, detection and accessory reagents for use on the intelliPATH automated stainer. Recommended staining protocols are specified in the datasheet of the antibody of interest. Pre-optimized intelliPATH protocols with preset parameters can be displayed, printed and edited according to the procedure in the Operator’s Manual. Refer to the Operator's Manual for additional instruction to navigate intelliPATH software and stainer. Use TBS for washing steps unless otherwise specified.

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. 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.
Troubleshooting:
Follow the antibody specific protocol recommendations according to the data sheet provided. If atypical results occur, contact Biocare's Technical Support at 1-800-542-2002.

References: