

CD30 (Ki-1)

Prediluted Monoclonal Antibody
901-031-081617

BIOCARE
M E D I C A L

Catalog Number:	PM 031 AA, H	IP 031 G10
Description:	6.0, 25 ml, prediluted	10 ml, prediluted
Dilution:	Ready-to-use	Ready-to-use
Diluent:	N/A	N/A

Intended Use:

For In Vitro Diagnostic Use

CD30 (Ki-1) [Ber-H2] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of CD30 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:

The CD30 antigen, initially designated Ki-1, recognizes a single chain transmembrane glycoprotein that has been demonstrated to be homologous to members of the nerve growth factor receptor superfamily. The mature 120 kDa molecule is formed from 90 kDa precursor molecule processed in the Golgi system. The Ki-1 (CD30) antigen is expressed in mononuclear Hodgkin's and multinucleated Reed-Sternberg cells in Hodgkin's disease. It is expressed by the tumor cells of a majority of anaplastic large cell lymphomas, and by a varying proportion of activated T and B cells. CD30 is also expressed on embryonal carcinomas. The CD30 monoclonal antibody from the Ber-H2 cell line was included in the Fourth International Workshop on Human Leukocyte Differentiation Antigens. It distinguishes large cell lymphomas derived from activated lymphoid cells, from histiocytic malignancies and lymphomas derived from resting and precursor lymphoid cells, or from anaplastic carcinomas. CD30 and CD15 primary antibodies may be used in tandem to differentiate between anaplastic large cell lymphoma and Hodgkin's disease (Reed-Sternberg cells).

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: Ber-H2

Isotype: IgG1/kappa

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

Epitope/Antigen: CD30

Cellular Localization: Cell membrane

Positive Control: Hodgkin's or anaplastic large cell lymphoma

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 (intelliPATH and manual use):

Peroxide Block: Block for 5 minutes with Biocare's Peroxidase 1.

Protocol Recommendations (intelliPATH and manual use)

Cont'd:

Pretreatment: Perform heat retrieval using Biocare's Diva Decloaker. Refer to the Diva Decloaker product data sheet for specific instructions.

Protein Block (Optional): Incubate for 5-10 minutes at RT with Biocare's Background Punisher.

Primary Antibody: Incubate for 30 minutes at RT.

Probe: Incubate for 10 minutes at RT with a secondary probe.

Polymer: Incubate for 10-20 minutes at RT with a tertiary polymer.

Chromogen:

Incubate for 5 minutes at RT with Biocare's DAB -OR- Incubate for 5-7 minutes at RT with Biocare's Warp Red.

Counterstain:

Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.

intelliPATH™ Automated Slide Stainer:

IP031 is intended for use on the intelliPATH™ Automated Slide Stainer. Refer to the intelliPATH Automated Slide Stainer manual for specific instructions on its use. When using the intelliPATH, peroxide block with intelliPATH Peroxidase Blocking Reagent (IPB5000) may be performed following heat retrieval.

Technical Note:

This antibody has been optimized for use with Biocare's MACH 4 Universal HRP-Polymer Detection and intelliPATH Universal HRP Detection Kit. 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 titers listed are not applicable to other detection systems, as results may vary. The data sheet recommendations and protocol 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) (7)

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Precautions Cont'd:

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. (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>.

References:

1. Tilly H, *et al.* Primary anaplastic large-cell lymphoma in adults: clinical presentation, immunophenotype, and outcome. *Blood*. 1997 Nov 1; 90 (9):3727-34.
2. Filippa DA, *et al.* CD30 (Ki-1) positive malignant lymphomas: clinical, immunophenotypic, histologic, and genetic characteristics and differences with Hodgkin's disease. *Blood*. 1996; Apr 1:87(7):2905-17.
3. Clavio M, *et al.* Anaplastic large cell lymphoma: a clinicopathologic study of 53 patients. *Leuk Lymphoma*. 1996 Jul;22(3-4):319-27.
4. Stein H, *et al.* Identification of Hodgkin and Sternberg-Reed cells as a unique cell type derived from a newly-detected small-cell population. *Int J Cancer*. 1982;30:445 -59.
5. Stein H, *et al.* The expression of the Hodgkin's disease associated antigen Ki-1 in reactive and neoplastic lymphoid tissue: evidence that Reed-Sternberg cells and histiocytic malignancies are derived from activated lymphoid cells. *Blood*. 1985;66:848-58.
6. Pallesen G, Hamilton-Dutoit SJ. Ki-1 (CD30) antigen is regularly expressed by tumor cells of embryonal carcinoma. *Am J Pathol*. 1988;133:446-50.
7. 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."
8. 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.

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.