



## CD30 (Ki-1)

Concentrated and Prediluted Monoclonal Antibody

Control Number: 901-346-072908

ISO  
9001:2000  
CERTIFIED

**Catalog Number:** CM 346 A,B,C  
**Description:** 0.1, 0.5, 1.0 ml, concentrated  
**Dilution:** 1:250-1:500  
**Diluent:** Renoir Red

PM 346 AA, H  
6.0, 25 ml, prediluted  
Ready-to-use  
N/A

**Pretreatment 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 20 minutes then wash in distilled water.

**Intended Use:**

For In Vitro Diagnostic Use

**Summary and Explanation:**

The Ki-1 antigen, 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 in embryonal carcinomas. 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 universal, affinity-purified, 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:** CON6D/B5

**Isotype:** IgG2a

**Epitope/Antigen:** CD30

**Cellular Localization:** Cell membrane

**Positive Control:** Hodgkin's or anaplastic large cell lymphoma

**Normal Tissue:** Tonsil

**Abnormal Tissue:** Hodgkin's or anaplastic large cell lymphoma

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

**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. Diluted reagents should be used promptly; any remaining reagent should be stored at 2°C to 8°C.

**Protocol Recommendations**

**Peroxide Block:**

If using an HRP system, block for 5 minutes with BIOCARE's PEROXIDAZED 1.

**Pretreatment Solution (recommended):** Diva or Reveal

**Protein Block:**

Incubate for 10-15 minutes at RT with BIOCARE's Background Sniper.

**Primary Antibody:** Incubate for 30 minutes at RT.

**Probe:** N/A

**Polymer:** Incubate for 30 minutes at RT with a Polymer.

**Chromogen:**

Incubate for 5 minutes at RT when using BIOCARE's DAB. - OR - Incubate for 10 minutes at RT when using BIOCARE's Vulcan Fast Red.

**Technical Note:**

This antibody has been standardized with BIOCARE's MACH 2 Mouse detection system. It can also be used on an automated staining system and with other BIOCARE polymer detection kits. Use TBS buffer for washing steps.

**Performance Characteristics:**

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. 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 NCCLS Quality Assurance for Immunocytochemistry approved guidelines, December 1999 MM4-A Vol.19 No.26 for more information about Tissue Controls.

**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 (NaN<sub>3</sub>) 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.

**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.

**Limitations and Warranty:**

There are no warranties, expressed or implied, which extend beyond this description. BIOCARE is not liable for property damage, personal injury, or economic loss caused by this product.



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CERTIFIED****References:**

1. Tilly H, et al. Primary anaplastic large-cell lymphoma in adults: clinical presentation, immunophenotype, and outcome. *Blood* 1997 Nov 1; 90 (9):3727-3734.
2. Filippa DA, Ladanyi M, Wollner N, Straus DJ, O'Brien JP, Portlock C, Gangi M, Sun M. CD30 (Ki-1) positive malignant lymphomas: clinical, immunophenotypic, histologic, and genetic characteristics and differences with Hodgkin's disease. *Blood* 1996; Apr 1:87(7):2905-2917.
3. Clavio M et al. Anaplastic large cell lymphoma: a clinicopathologic study of 53 patients. *Leuk Lymphoma* 1996 Jul;22(3-4):319-327
4. Stein H, Gerdes J, Schwab U, Lemke H, Mason DY, Ziegler A, 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, Mason fly, Gerdes J, O'Connor N, Wainscoat J, Pallesen G, 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. National Committee for Clinical Laboratory Standards(NCCLS). Protection of laboratory workers from infectious diseases transmitted by blood and tissue; proposed guideline. Villanova, PA 1991;7(9). Order code M29-P.



## CD30 (Ki-1)

### Prediluted Mouse Monoclonal Antibody

Control Number: 901-346IP-051908

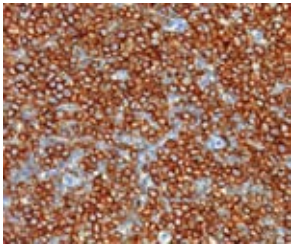
<b>Catalog Number:</b>	<b>Description:</b>
IP 346 G10	10 ml, predilute
IP 346 G20	20 ml, predilute

#### Intended Use:

For In Vitro Diagnostic Use

#### Summary and Explanation:

The Ki-1 antigen, 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. 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).



Hodgkins lymphoma stained with CD30 monoclonal 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, an affinity-purified, 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:** CON6D/B5

**Isotype:** IgG2a

**Antibody Category:** Lymphoma

**Epitope/Antigen:** CD30

**Total Protein Concentration:** Call for lot specific Ig Concentration.

**Cellular Localization:** Cell membrane

**Positive Control:** Hodgkin's or anaplastic large cell lymphoma

**Normal Tissue:** Tonsil

**Abnormal Tissue:** 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. Diluted reagents should be used promptly; any remaining reagent should be stored at 2°C to 8°C.

#### Protocol Recommendations

**Pretreatment Solution (recommended):** Diva

#### Pretreatment Protocol:

Heat Retrieval Method:

Retrieve sections under pressure using BIOCARE's Decloaking Chamber as followed by a wash in distilled water. Alternatively, steam tissue sections for 45-60 minutes. Allow solution to cool for 20 minutes then wash in distilled water.

#### Peroxide Block:

Block for 5 minutes at RT.

**Primary Antibody:** Incubate for 30 minutes at RT.

**Secondary:** Incubate for 10 minutes at RT.

**Tertiary:** Incubate for 10 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.

#### Quality Statement:

BIOCARE protocols have been standardized using in-house antibodies, detection and accessory reagents for use on the *intelliPATH* FLX automated stainer. Recommended staining protocols are specified in the datasheet of the antibody of interest. Pre-optimized *intelliPATH* FLX 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* FLX software and stainer. Use TBS for washing steps unless otherwise specified.

#### Performance Characteristics:

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. 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:

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**Troubleshooting:**

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