CD19
Concentrated and Prediluted Monoclonal Antibody
901-310-030618

<table>
<thead>
<tr>
<th>Catalog Number:</th>
<th>Description:</th>
<th>Diluent:</th>
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<tbody>
<tr>
<td>CM 310 A, B</td>
<td>0.1, 0.5 ml, concentrated</td>
<td>Renoir Red</td>
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<tr>
<td>PM 310 AA</td>
<td>6.0 ml, prediluted</td>
<td>N/A</td>
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</tbody>
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**Intended Use:**
For In Vitro Diagnostic Use
CD19 is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of CD19 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:**
CD19 recognizes a 95kD cell surface glycoprotein, which is expressed by cells of the B-cell lineage and follicular dendritic cells. CD19 is a co-receptor of CD21 and is an important signal transduction molecule which is involved in the regulation of B lymphocyte development, activation and differentiation. Among the B-cell genes that are present in early B-cell development and are upregulated by Pax-5 are CD19 and CD79a. CD19 is found in pre-B cells, B cells (considered a pan B-cell antigen); first B-cell antigen after HLA-DR and follicular dendritic cells. CD19 is absent in plasma cells, most T-cell lymphomas and in lymphocyte predominant Hodgkin’s. It has been observed in lymphomas and leukemias but often weak/negative in follicular lymphoma or diffuse large B-cell lymphoma.

**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 enzyme labeled polymer is added to bind to the primary antibody. This detection of the bound antibody is evidenced by a colorimetric reaction.

**Source:** Mouse monoclonal
**Species Reactivity:** Human; others not tested
**Clone:** CD19
**Isotype:** IgG1
**Total Protein Concentration:** ~10 mg/ml. Call for lot specific Ig concentration.

**Epitope/Antigen:** CD19
**Cellular Localization:** Cytoplasmic/cell membrane

**Quality Control:**

**Recommendations:**
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 (Na₃) 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) (5)
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. (6)
3. Microbial contamination of reagents may result in an increase in nonspecific staining.
4. Incubation times or temperatures other than those specified may vary. These include, but are not limited to fixed paraffin, heat-retrieval method, incubation times, tissue section thickness and fixation 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. 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.

**Protocol Recommendations Cont’d:**

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**Peroxide Block:** Block for 5 minutes with Biocare’s Peroxidazed 1.
**Preparation:** Perform heat retrieval using Biocare’s Diva or Reveal Decloaker. Refer to the Diva or Reveal 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.
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: