CD11c (Leu-M5)

Concentrated and Prediluted Monoclonal Antibody
901-3122-122117

BIOCARE MEDICAL

Catalog Number:	**ACI 3122 A, B**	**API 3122 AA**
Description:	0.1, 0.5 ml, concentrated	6.0 ml, prediluted
Dilution:	1:100	Ready-to-use
Diluent	Renoir Red	N/A

Intended Use:
For In Vitro Diagnostic Use
CD11c (Leu-M5) [5D11] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of CD11c 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:
CD11c (also known as Leu-M5 or Integrin alpha X) [5D11] is a member of the leukointegrin family. CD11c is a cell surface adhesion receptor and is predominantly expressed in tissue macrophages, dendritic cells, monocytes, NK cells and granulocytes. CD11c has been shown to be both sensitive and specific for hairy cell leukemia (HCL) (1). CD11c can be used to differentiate hairy cell leukemia from other small B-cell lymphomas (1). Vardiman *et al* demonstrated that when a bone marrow biopsy showed HCL, virtually all leukemic cells were positive for CD11c (2). In another study, all hairy cell leukemia cases were positive for CD11c and negative for CD5 (3). A panel of CD103, CD11c, CD25, CD5, CD10 and CD23 has been useful in definitively diagnosing hairy cell leukemia (3). Chronic myelomonocytic leukemia monocytes display a population of monocytes with CD11c underexpression which may aid in the diagnosis of chronic myelomonocytic leukemia (4). A panel using CD20 and/or DBA.44 as well as either TRAP, CD11c or Annexin A1 improves specificity when evaluating normal lymphocytes from hairy cells (5).
Dendritic cells play a key role in immunosurveillance. CD11c marks dendritic cells and was evaluated with regard to high-grade cervical intraepithelial neoplasia and prognosis. Specimens with higher rates of CD4+ T-cells, CD11c+ dendritic cells and T-bet+ transcription factors showed a strong correlation with favorable clinical outcomes (6). In a separate study, CD11c positive dendritic cells were dramatically reduced and macrophages were significantly increased in the skin of immunosuppressed renal transplant recipients which may correlate with increased risk of squamous cell carcinoma in these patients (7).

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: 5D11
Isotype: IgG2a
Total Protein Concentration: ~10 mg/ml. Call for lot specific Ig concentration.
Epitope/Antigen: CD11c
Cellular Localization: Cell membrane
Positive Tissue Control: Skin
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. Diluted reagents should be used promptly; any remaining reagent should be stored at 2ºC to 8ºC.

Protocol Recommendations:
Peroxide Block: Block for 5 minutes with Biocare's Peroxidazed 1.
Pretreatment: Perform heat retrieval using Biocare's Diva Decloaker. Refer to the Diva Decloaker 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.
Technical Note:
This antibody has been standardized with Biocare's MACH 4 detection system. Use TBS buffer 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 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.
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 (NaN_3) 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) (8)
2. Specimens, before and after fixation, and all materials exposed to them should be handled as if capable of transmitting infection and

Biocare Medical
60 Berry Drive
Pacheco, CA 94553
USA

IVD CE

Rev: 062117

EC REP EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Tel: 800-799-9499 | www.biocare.net | Fax: 925-603-8080

Precautions Cont'd:
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. (9)
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:
1. Johrens K, *et al.* A novel CD11c monoclonal antibody effective in formalin-fixed tissue for the diagnosis of hairy cell leukemia. Pathobiology. 2008; 75(4):252-6.
2. Vardiman JW, *et al.* Evaluation of Leu-M5 (CD11c) in hairy cell leukemia by the alkaline phosphatase anti-alkaline phosphatase technique. Am J Clin Pathol. 1988 Sep; 90(3):250-6.
3. Chen YH, *et al.* Immunophenotypic variations in hairy cell leukemia. Am J Clin Pathol. 2006 Feb; 125(2):251-9.
4. Sojitra P, *et al.* Chronic myelomonocytic leukemia monocytes uniformly display a population of monocytes with CD11c underexpression. Am J Clin Pathol. 2013 Nov; 140(5):686-92.
5. Noel P. Definition of remission, minimal residual disease, and relapse in hairy cell leukemia bone marrow biopsy histology and immunohistology specimens. Leuk Lymphoma. 2011 Jun; 52 Suppl 2:62-4.
6. Origoni M, *et al.* Prognostic significance of immunohistochemical phenotypes in patients treated for high-grade cervical intraepithelial neoplasia. Biomed Res Int. 2013; 2013:831907.
7. Sandvik LF, *et al.* CD11c(+) dendritic cells rather than Langerhans cells are reduced in normal skin of immunosuppressed renal transplant recipients. Acta Derm Venereol. 2014 Mar; 94(2):173-8.
8. 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."
9. 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.

Biocare Medical
60 Berry Drive
Pacheco, CA 94553
USA

IVD CE

Rev: 062117

EC REP EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Tel: 800-799-9499 | www.biocare.net | Fax: 925-603-8080