CD43

Concentrated and Prediluted Monoclonal Antibody 901-005-121417



Catalog Number:	CM 005 A, C	PM 005 AA	IP 005 G10
Description:	0.1, 1.0 ml, concentrated	6.0 ml, prediluted	10 ml, prediluted
Dilution:	1:100	Ready-to-use	Ready-to-use
Diluent:	Monet Blue	N/A	N/A

Intended Use:

For In Vitro Diagnostic Use

CD43 [DF-T1] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of CD43 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:

Studies have shown CD43 recognizes a 95/115/135 kDa (depending upon the extent of glycosylation) cell surface glycoprotein, identified as CD43 (leukosialin, sialophorin, or leukocyte sialoglycoprotein) (4th Leucocyte Workshop). CD43 is expressed on all thymocytes and T-cells (1-6). This antibody has been shown to aid in the identification and classification of T-cell malignancies and low grade B-cell lymphomas.

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: DF-T1

Isotype: IgG1

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

Epitope/Antigen: CD43

Cellular Localization: Cell surface

Positive Tissue 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 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 (intelliPATH and manual use): Peroxide Block: Block for 5 minutes with Biocare's Peroxidazed 1.

Pretreatment: 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.

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.

<u>Protocol Recommendations (intelliPATH and manual use)</u> <u>Cont'd:</u>

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

intelliPATH[™] Automated Slide Stainer:

IP005 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 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 (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)

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 reagents after the expiration date printed on the vial.

Biocare Medical 60 Berry Drive

Pacheco, CA 94553

USA

IVD CE



CD43

Concentrated and Prediluted Monoclonal Antibody 901-005-121417

Precautions Cont'd:

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 at1-800-542-2002.

References:

1. Muretto P. An immunohistochemical study on fetuses and newborns lymph nodes with emphasis on follicular dendritic cells. Eur J of Histochem. 1995; 39(4):301-8.

2. de Smet W, Walter H, van Hove L. A new CD43 monoclonal antibody induces homotypic aggregation of human leucocytes through a CD11a/CD18-dependent and -independent mechanism. Immunology. 1993; 79(1):46-54.

3. Bo L, Mork S, Nyland H. An immunohistochemical study of mononuclear cells in meningiomas. Neuropathol Appl Neurobiol. 1992; 18(6):548-58.

4. Petruch UR, Horny HP, Kaiserling E. Frequent expression of haemopoietic and non-haemopoietic antigens by neoplastic plasma cells: an immunohistochemical study using formalin-fixed, paraffin-embedded tissue. Histopathology. 1992; 20(1):35-40.

5. Anderson *C, et al.* Methods in pathology. Identification of T-cell lymphomas in paraffin-embedded tissues using polyclonal anti-CD3 antibody: comparison with frozen section immunophenotyping and genotypic analysis. Mod Pathol. 1991; 4(3):358-62.

6. Stross WP, *et al.* Molecule detected in formalin fixed tissue by antibodies MT1, DF-T1, and L60 (Leu-22) corresponds to CD43 antigen. J Clin Pathol. 1989; 42(9):953-61.

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.



The Netherlands



Rev: 062117
Tel: 800-799-9499 | www.biocare.net | Fax: 925-603-8080