CD4 + CD8

Prediluted Multiplex Antibody Reagent
901-3157DS-060123

BIOCARE MEDICAL

Available Product Formats				
Format	Catalog Number	Description	Dilution	Diluent
ONCORE Pro	OPAI 3157DS T60	60 tests	Ready-to-use	N/A

Intended Use:
For In Vitro Diagnostic Use
CD4 + CD8 is a cocktail of mouse monoclonal and rabbit monoclonal antibodies that is intended for laboratory use in the qualitative identification of CD4 and CD8 proteins 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:
CD4 is expressed in a T-cell subset (helper/inducer) and is found in approximately 80% of thymocytes and in 45% of peripheral blood lymphocytes. CD4 is expressed in the majority of T-cell lymphomas including mycosis fungoides, a common form of cutaneous T-cell lymphoma.[1] CD8 has been shown to be an important marker in the analysis of T-cell mediated inflammatory dermatoses and is also useful for analysis of mycosis fungoides.[2-4] CD8 can be used in panels with CD4, CD56, TIA-1 to aid in identifying subsets of inflammatory skin diseases.[4] CD4 and CD8 have also been shown to be valuable in squamous cell cervical cancer and gastric mucosa in HIV infection (5-7). The combination of CD4(+) and CD8(-) is helpful in distinguishing mycosis fungoides and can be used in a panel of CD2(+), CD3(+) and CD7(-/+).[1-3]

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 one-step or two-step detection procedure can be applied. A one-step procedure will feature an enzyme labeled polymer that binds the primary antibody. A two-step procedure will feature a linker antibody added to bind to the primary antibody. An enzyme-labeled polymer is then added to bind the linker antibody. These detections of the bound antibodies are evidenced by a colorimetric reaction.

Reagent Provided:
CD4 + CD8 is provided as a prediluted antibody cocktail of anti-CD4 and anti-CD8 antibodies in buffer with carrier protein and preservative.

Antibody	anti-CD4	anti-CD8
Clone	4B12	SP16
Source	Mouse monoclonal	Rabbit monoclonal
Isotype	IgG1/kappa	IgG
Epitope/ Antigen	CD4	CD8
Cellular Localization	Cell surface	Cell surface
Staining	Brown (DAB)	Red (Warp Red)

Species Reactivity: Human; others not tested
Positive Tissue Control: Mycosis fungoides and normal tonsil
Known Applications:
Immunohistochemistry (formalin-fixed paraffin-embedded tissues)
Storage and Stability:
Store at 2ºC to 8ºC. The product is stable to the expiration date printed on the label, when stored under these conditions. Do not use after expiration date. Diluted reagents should be used promptly; any remaining reagent should be stored at 2ºC to 8ºC.

Protocol Recommendations (ONCORE™ Pro Automated Slide Staining System):
OPAI3157DS is intended for use with the ONCORE Pro. Refer to the User Manual for specific instructions for use. Protocol parameters in the Protocol Editor should be programmed as follows:
Protocol Name: CD4 + CD8
Protocol Template (Description): Specials Template (Mouse Amp and Multiplex 2 Detections Required)
Dewaxing (DS Option): DS2-50
Antigen Retrieval (AR Option): AR1, high pH; 103°C
Reagent Name, Time, Temp.: CD4 + CD8, 30 min., 25°C

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.
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)[9]
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.[10]
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. Boone SL, Guitart J, Gerami P. Follicular mycosis fungoides: a histopathologic, immunohistochemical, and genotypic review. G Ital Dermatol Nenereol. 2008 Dec;143 (6):409-14.
2. Hodak E, *et al.* CD4/CD8 double-negative epidermotropic cutaneous T-cell lymphoma: an immunohistochemical variant of mycosis fungoides. J Am Acad Dermatol. 2006 Aug;55(2):276-84.
3. Tirumalae R, Panjwani PK. Origin Use of CD4, CD8, and CD1a Immunostains in Distinguishing Mycosis Fungoides from its Inflammatory Mimics: A Pilot Study. Indian J Dermatol. 2012 Nov;57(6):424-7.

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References Cont'd:
4. Harvell JD, Nowfar-Rad M, Sundram U. An immunohistochemical study of CD4, CD8, TIA-1 and CD56 subsets in inflammatory skin disease. J Cutan Pathol. 2003 Feb;30(2):108-13.
5. Shi Z, *et al.* Frequency, distribution of CD4+, CD8+ T cells and expression of CD38 in gastric mucosa of HIV infections. Za Zhi. 2009 Aug;23(4):261-4.
6. Shah W, *et al.* A reversed CD4/CD8 ratio of tumor-infiltrating lymphocytes and a high percentage of CD4(+)FOXP3(+) regulatory T cells are significantly associated with clinical outcome in squamous cell carcinoma of the cervix. Cell Mol Immunol. 2011 Jan;8(1):59-66.
7. Barth TF, *et al.* Primary gastric apoptosis-rich T-cell lymphoma co-expressing CD4, CD8, and cytotoxic molecules. Virchows Arch. 2000 Apr; 436(4):357-64.
8. Williamson SL, *et al.* New monoclonal antibodies to the T cell antigens CD4 and CD8. Production and characterization in formalin-fixed paraffin-embedded tissue. Am J Pathol. 1998 Jun; 152(6):1421-6.
9. 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."
10. 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.

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