CONFIRM anti-CD5 (SP19) Rabbit Monoclonal Primary Antibody

REF 790-4451

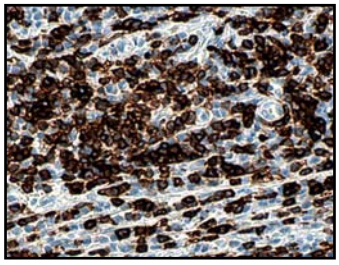

Figure 1 CONFIRM anti-CD5 (SP19) Rabbit Monoclonal Primary Antibody membrane or cytoplasmic staining of T cells in lymphoma

INTENDED USE

Ventana Medical Systems' (Ventana) CONFIRM anti-CD5 (SP19) Rabbit Monoclonal Primary Antibody is directed against human CD5 expressed on the plasma membrane of virtually all human T cells and the B1a subset of human B cells found in the follicular mantle zones, bone marrow and peripheral blood. Staining CD5 is commonly used as part of several IHC panels to determine T cell and B cell sub-classifications. CD5 may be used to aid in the identification of T cell lymphomas, and certain B cell lymphomas, including mantle cell lymphoma. The antibody is intended for qualitative staining in sections of formalin fixed, paraffin embedded tissue.

This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls.

This antibody is intended for *in vitro* diagnostic (IVD) use.

SUMMARY AND EXPLANATION

CD5 is a single chain transmembrane glycoprotein that appears early in thymocyte development. CD5 is expressed at low levels in thymocytes and high levels in T lymphocytes.[3] CD5 is also expressed by the B1a subset of human B lymphocytes.[4] CD5 acts as a coreceptor in the modulation of antigen-specific receptor-mediated activation and differentiation signals. In thymocytes and B1a cells, CD5 appears to provide inhibitory signals, while in mature T lymphocytes it acts as a co-stimulatory receptor.[3] Anti-CD5 can be used as part of a panel of antibodies to classify T cell disorders including T cell lymphomas ,[3] and certain B cell disorders such as mantle cell lymphoma.[5,6]

REAGENT PROVIDED

CONFIRM anti-CD5 (SP19) Rabbit Monoclonal Primary Antibody contains sufficient reagent for staining 50 tests.

One 5 mL dispenser of CONFIRM anti-CD5 contains approximately 3.75 µg of a rabbit monoclonal (SP19) antibody.

The antibody is diluted in 0.05 M Tris-HCL with 1% carrier protein and 0.10% ProClin 300, a preservative.

Total protein concentration of the reagent is approximately 10 mg/mL. Specific antibody concentration is approximately 0.75 µg/mL. There is no known non-specific antibody reactivity observed in this product.

CONFIRM anti-CD5 is a rabbit monoclonal antibody.

This antibody is optimized for use on a Ventana automated slide stainer in combination with Ventana detection kits. No reconstitution, mixing, dilution, or titration is required.

Refer to the appropriate Ventana detection kit package insert for detailed descriptions of: (1) Principles and Procedures, (2) Materials and Reagents Needed but Not Provided, (3) Specimen Collection and Preparation for Analysis, (4) Quality Control Procedures, (5) Troubleshooting, (6) Interpretation of Results, and (7) General Limitations.

MATERIALS REQUIRED BUT NOT PROVIDED

Staining reagents such as Ventana detection kits (i.e., *ultra*View Universal DAB Detection Kit), and ancillary components, including negative and positive tissue control slides, are not provided.

STORAGE

Store at 2–8°C. Do not freeze.

To ensure proper reagent delivery and the stability of the antibody, replace the dispenser cap after every use and immediately place the dispenser in the refrigerator in an upright position.

Every antibody dispenser is expiration dated. When properly stored, the reagent is stable to the date indicated on the label. Do not use reagent beyond the expiration date.

SPECIMEN PREPARATION

Routinely processed, formalin fixed, paraffin embedded tissues are suitable for use with this primary antibody when used with Ventana detection kits and a Ventana automated slide stainer. The recommended tissue fixative is 10% neutral buffered formalin.[2] Slides should be stained immediately, as antigenicity of cut tissue sections may diminish over time.

It is recommended that positive and negative controls be run simultaneously with unknown specimens.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. This product contains 1% or less bovine serum which is used in the manufacture of the antibody.
3. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
4. Avoid microbial contamination of reagents.
5. Consult local and/or state authorities with regard to recommended method of disposal.

STAINING PROCEDURE

Ventana primary antibodies have been developed for use on a Ventana automated slide stainer in combination with Ventana detection kits and accessories. Recommended staining protocols for BenchMark XT and BenchMark ULTRA instruments with *ultra*View Universal DAB Detection Kit are listed in Table 1.

The parameters for the automated procedures can be displayed, printed and edited according to the procedure in the instrument's Operator's Manual. Refer to the appropriate Ventana detection package insert for more details regarding immunohistochemistry staining procedures.

Table 1. Recommended Staining Protocols for CONFIRM anti-CD5 (SP19) Rabbit Monoclonal Primary Antibody with *ultra*View Universal DAB Detection Kit on BenchMark XT/BenchMark ULTRA instruments.`

Procedure Type	Method
Deparaffinization	Selected
Cell Conditioning (Antigen Unmasking)	Standard Cell Conditioning 1
Enzyme (Protease)	None required
Antibody (Primary)	BenchMark XT instrument Approximately 16 minutes, 37°C BenchMark ULTRA instrument Approximately 16 minutes, 36°C
Counterstain	Hematoxylin II, 4 minutes
Post Counterstain	Bluing Reagent, 4 minutes

Due to variation in tissue fixation and processing, as well as general lab instrument and environmental conditions, it may be necessary to increase or decrease the primary antibody incubation and cell conditioning based on individual specimens, detection used, and reader preference. For further information on fixation variables, refer to "Immunohistochemistry Principles and Advances."[1]

POSITIVE TISSUE CONTROL

Examples of positive control tissues for CONFIRM anti-CD5 (SP19) Rabbit Monoclonal Primary Antibody are normal tonsil and lymphoma.

STAINING INTERPRETATION

The cellular staining pattern for CONFIRM anti-CD5 (SP19) Rabbit Monoclonal Primary Antibody is cell membrane or cytoplasmic.

SPECIFIC LIMITATIONS

CONFIRM anti-CD5 (SP19) Rabbit Monoclonal Primary Antibody has been optimized on BenchMark XT and BenchMark ULTRA instruments in combination with *ultra*View Universal DAB Detection Kit (REF 760-500) at a 16 minute primary antibody incubation time; however, the user must validate individual laboratory results obtained with this reagent.

PERFORMANCE CHARACTERISTICS

1. Specificity of CONFIRM anti-CD5 (SP19) Rabbit Monoclonal Primary Antibody was determined by testing formalin fixed, paraffin embedded normal and neoplastic tissues.

   For normal tissues, results are as follows: (0/3) cerebrum, (0/3) cerebellum, (0/3) adrenal gland, (0/2) ovary, (0/3) pancreas, (0/2) parathyroid gland, (0/3) hypophysis, (0/3) testis, (0/3) thyroid gland, (0/3) breast, (3/3) spleen, (3/3) tonsil, (3/3) thymus, (0/3) bone marrow, (0/3) lung, (0/3) heart, (0/3) esophagus, (0/2) gastric fundus, (0/3) small intestine, (0/3) colon, (0/3) liver, (0/3) salivary gland, (0/3) kidney, (0/3) prostate, (0/3) endometrium, (0/3) cervix, (0/3) skeletal muscle, (0/3) skin , (0/3) nerve, (0/3) mesothelium and lung.

   For neoplastic tissues, results are as follows: (0/1) glioblastoma, (0/1) atypical meningioma, (0/1) malignant ependymoma, (0/1) malignant oligodendroglioma, (0/1) ovarian serous papillary adencarcinoma, (0/1) ovarian mucinous papillary adenocarcinoma , (0/1) islet cell carcinoma, (0/1) pancreatic adenocarcinoma, (0/1) seminoma, (0/1) embryonal carcinoma, (0/1) medullary carcinoma, (0/1) papillary carcinoma, (0/1) intraductal carcinoma, (0/2) breast lobular carcinoma in situ, (0/1) invasive ductal carcinoma,(0/1) diffuse B cell lymphoma, (0/1) small cell undifferentiated carcinoma, (0/1) lung squamous cell carcinoma with necrosis , (0/1) lung adenocarcinoma , (0/1) esophageal squamous cell carcinoma, (0/1) esophageal adenocarcinoma, (0/1) mucinous adenocarcinoma, (0/1) small intestine adenocarcinoma , (0/1) small intestine intermediate grade interstitialoma , (0/1) colon adenocarcinoma (0/1) colon intermediate grade interstitialoma, (0/1) rectum adenocarcinoma, (0/1) rectum intermediate grade interstitialoma, (0/1) hepatocellular carcinoma, (0/1) heptaoblastoma, (0/1) clear cell carcinoma, (0/1) prostate adenocarcinoma, (0/1) transitional cell carcinoma, (0/1) leiomyoma, (0/1) endometrial adenocarcinoma, (0/1) endometrial clear cell carcinoma, (0/2) uterine cervix squamous cell carcinoma, (0/1) embryonal rhabdomyosarcoma, (0/1) malignant melanoma, (0/1) basal cell carcinoma, (0/1) squamous cell carcinoma, (0/1) neurofinroma, (0/1) neuroblastoma, (0/1) epithelial malignant mesothelioma, (1/2) diffuse malignant lymphoma, (0/1) Hodgkin's lymphoma of supraclavicular, (0/1) diffuse malignant lymphoma, (0/1) transitional cell carcinoma with squamous metaplasia, (0/1) low grade leiomyosarcoma, (0/1) osteosarcoma, (0/1) spindle cell rhabdmyosarcoma, (0/1) intermediate grade leiomyosarcoma. (13/80) diffuse large cell lymphoma, (1/3) lymphoblastic lymphoma, (3/10) small lymphocytic lymphoma, (0/7) follicular lymphoma, (0/12) Hodgkins lymphoma, (0/6) anaplastic large cell lymphoma, (3/5) mantle cell lymphoma, (0/9) mucosa associated lymphoma, (7/8) T cell lymphoma, (0/1) Burkitt like lymphoma .[7,8]
2. Lot to lot reproducibility was determined by testing 3 lots across 1 multi-tissue block (3 tissues per block) on a BenchMark XT instrument. 3 out of 3 samples across all 3 lots scored equivalently.
3. Inter-run repeatability was determined by staining 2 multi-tissue blocks (3 tissues per block for a total of 6 tissues) across 5 slides on a BenchMark XT instrument over a five day non-consecutive period. 150 out of 150 samples tested scored equivalently.
4. Intra-run repeatability was determined by staining 2 multi tissue blocks (3 tissues per block for a total of 6 tissues) across 14 slides on a BenchMark XT instrument. 84 out of 84 samples tested scored equivalently.
5. Intra-platform repeatability was determined by staining 2 multi-tissue blocks (3 tissues per block) across 5 slides on 3 BenchMark XT instruments. 90 out of 90 samples tested scored equivalently.
6. Inter-platform repeatability was determined by staining 1 multi-tissue block (3 tissues per block) across 5 slides on 3 BenchMark XT instruments and 3 BenchMark ULTRA instruments. 90 out of 90 samples tested scored equivalently.
7. Compatible with *i*VIEW DAB and *ultra*View Universal DAB Detection Kits.

REFERENCES

1. Dalloul A. CD5: A safeguard against autoimmunity and a shield for cancer cells. Autoimmun 2009;8:349-353.
2. Dono M, Cerruti G, Zupo S. The CD5+ B cell. Int J Biochem Cell Biol 2004;36:2105-2111.
3. De Leon ED, Alkan S, Huang JC, His ED. Usefulness of an immunohistochemical panel in paraffin-embedded tissues for the differentiation of B cell non-Hodgkin's lymphomas of small lymphocytes. Mod Pathol 1998;11:1046-1051.
4. Cabezudo E, Carrara P, Morilla R, Matutes E. Quantitative analysis of CD79b, CD5 and CD19 in mature B cell lymphoproliferative disorders. Hematologica 1999;84:413-418.
5. Sheehan DC, Hrapchak BB. Theory and Practice of Histotechnology. 2nd Edition. St. Louis, MO: The C.V. Mosby Company; 1980.
6. Roche PC, Hsi ED. Immunohistochemistry-Principles and Advances. Manual of Clinical Laboratory Immunology. 6th edition. In: Rose NR, ed. ASM Press; 2002.
7. Matolcsy A, Chadburn A, Knowles D. De Novo CD5-postive and Richter's syndrome-associated diffuse large B cell lymphomas are genotypically distinct. Am J Pathol 1995;147:207-216.
8. Suguro M, Tagawa H; Kagami Y, et al. Expression profiling analysis of the CD5+ diffuse large B cell lymphoma subgroup: Development of a CD5 signature. Cancer Sci 2006;97:868-874.

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