

VENTANA anti-CD10 (SP67) Rabbit Monoclonal Primary Antibody

REF

790-4506

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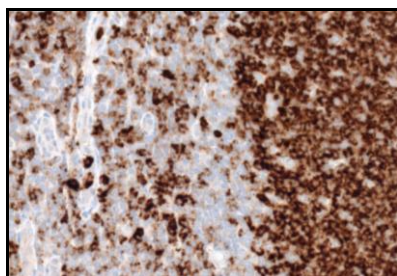
IVD
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Figure 1. VENTANA anti-CD10 (SP67) exhibiting a membrane and/or cytoplasmic staining pattern in lymphoma tissue.

INTENDED USE

VENTANA anti-CD10 (SP67) Rabbit Monoclonal Primary Antibody is directed against the CD10 molecule, or common acute lymphoblastic leukemia antigen (CALLA), expressed on the surface of early lymphoid cells, and on various nonlymphoid tissues including breast myoepithelial cells, bile canaliculi, fibroblasts, kidney tubular brush borders and small intestine epithelium. This antibody exhibits a cell

membranous and/or cytoplasmic staining pattern and may be used to aid in the identification of Burkitt's lymphoma and follicular germ cell lymphoma, and in the classification of some carcinomas such as renal cell carcinoma. 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

VENTANA anti-CD10 (SP67) is a recombinant rabbit monoclonal antibody. CD10, or the common acute lymphoblastic leukemia antigen (CALLA), is a 90- to 110-kd integral membrane glycoprotein.¹ Despite its initial identification as a marker for acute lymphoblastic leukemias (ALLs), CD10 functions as a neutral metalloendopeptidase, which cleaves a variety of biologically active peptides.^{2,3} CD10 is expressed in a variety of normal tissue types, including early lymphoid cells, and various leukemias and lymphomas.⁴ Detection of CD10 is useful in the characterization of a subset of malignant lymphomas, including precursor B-lymphoblastic lymphoma, follicular center cell lymphoma, and Burkitt lymphoma, in which CD10 is frequently expressed.⁵ In addition, CD10 may be used as part of a panel of markers for suspected clear cell or papillary renal carcinoma, as CD10 expression is strong in nearly all of these neoplasms.⁶

PRINCIPLE OF THE PROCEDURE

VENTANA anti-CD10 (SP67) is a rabbit monoclonal antibody produced against a synthetic peptide corresponding to the human CD10 protein. VENTANA anti-CD10 (SP67) binds to the CD10 protein in paraffin-embedded tissue sections and exhibits a membrane and/or cytoplasmic staining pattern. This antibody can be visualized using OptiView DAB IHC Detection Kit (Cat. No. 760-700/06396500001) or *ultra*View Universal DAB Detection Kit (Cat. No. 760-500/05269806001). Refer to the OptiView DAB IHC Detection Kit or *ultra*View Universal DAB Detection Kit package inserts for further information.

REAGENT PROVIDED

VENTANA anti-CD10 (SP67) contains sufficient reagent for 50 tests.

One 5 mL dispenser of VENTANA anti-CD10 (SP67) contains approximately 24.5 µg of a rabbit monoclonal antibody.

The antibody is diluted in phosphate buffered saline containing carrier protein and 0.05% ProClin 300 as a preservative.

Total protein concentration of the reagent is approximately 3 mg/mL. Specific antibody concentration is approximately 4.9 µg/mL. There is no known non-specific antibody reactivity observed in this product.

VENTANA anti-CD10 (SP67) is a recombinant monoclonal antibody produced from purified cell culture supernatant.

Refer to the appropriate VENTANA detection kit package insert for detailed descriptions of: (1) Principles of the Procedure, (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 and ancillary components, including negative and positive tissue control slides, are not provided.

Not all products listed in the package insert may be available in all geographies. Consult your local support representative.

STORAGE

Upon receipt and when not in use, 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 BenchMark IHC/ISH series of automated instruments. The recommended tissue fixative is 10% neutral buffered formalin.⁷ 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 (IVD) use.
2. For professional use only.
3. ProClin 300 solution is used as a preservative in this reagent. It is classified as an irritant and may cause sensitization through skin contact. Take reasonable precautions when handling. Avoid contact of reagents with eyes, skin, and mucous membranes. Use protective clothing and gloves.
4. Materials of human or animal origin should be handled as biohazardous materials and disposed of with proper precautions.
5. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
6. Avoid microbial contamination of reagents as it may cause incorrect results.
7. Consult local and/or state authorities with regard to recommended method of disposal.
8. For supplementary safety information, refer to the product Safety Data Sheet and the Symbol and Hazard Guide located at www.ventana.com.

STAINING PROCEDURE

VENTANA primary antibodies have been developed for use on BenchMark IHC/ISH instruments in combination with VENTANA detection kits and accessories. Refer to Table 1 and Table 2 for recommended staining protocols.

This antibody has been optimized for specific incubation times but the user must validate results obtained with this reagent.

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

Table 1. Recommended Staining Protocol for VENTANA anti-CD10 (SP67) with OptiView DAB IHC detection on a BenchMark XT instrument, BenchMark GX instrument, and BenchMark ULTRA instrument.

Procedure Type	Method
Deparaffinization	Selected
Cell Conditioning (Antigen Unmasking)	Cell Conditioning 1 BenchMark ULTRA instrument: 92 min BenchMark XT instrument: 92 min BenchMark GX instrument 92 min
Pre-primary peroxidase inhibition	Selected
Antibody (Primary)	BenchMark ULTRA instrument 28 min, 36°C BenchMark XT instrument 12 min, 37°C BenchMark GX instrument 32 min, 37°C
Amplification	ULTRA (8/8 min), XT (12/12 min), GX (8/8 min)
Counterstain	Hematoxylin II, 4 min
Post Counterstain	Bluing, 4 min

* Amplification Kit (REF 760-099)

Table 2. Recommended Staining Protocol for VENTANA anti-CD10 (SP67) *ultraView* Universal DAB IHC on a BenchMark XT instrument, BenchMark GX instrument, and BenchMark ULTRA instrument.

Procedure Type	Method
Deparaffinization	Selected
Cell Conditioning (Antigen Unmasking)	Cell Conditioning 1 BenchMark ULTRA instrument: 92 min BenchMark XT instrument: Extended (90 min) BenchMark GX instrument: Extended (90 min)
Antibody (Primary)	BenchMark ULTRA instrument 20 min, 36°C BenchMark XT instrument 16 min, 37°C BenchMark GX instrument 28 min, 37°C
Amplification*	ULTRA (Rabbit), XT, GX
Counterstain	Hematoxylin II, 4 min
Post Counterstain	Bluing, 4 min

* Amplification Kit (REF 760-080)

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, cell conditioning or protease pretreatment based on individual

specimens, detection used, and reader preference. For further information on fixation variables, refer to "Immunohistochemistry Principles and Advances." ⁸

POSITIVE TISSUE CONTROL

The recommended positive control tissue is normal tonsil or lymph node. Germinal center B-cells should demonstrate a moderate but distinct membranous staining pattern. Neutrophils and endothelial cells should also stain positively. Mantle zone B-cells and squamous epithelial cells should be negative.

STAINING INTERPRETATION / EXPECTED RESULTS

The cellular staining pattern for VENTANA anti-CD10 (SP67) is membranous and/or cytoplasmic.

SPECIFIC LIMITATIONS

OptiView detection system is generally more sensitive than the *ultraView* detection system. The user must validate the results obtained with this reagent and detection systems.

PERFORMANCE CHARACTERISTICS

Staining tests for specificity, sensitivity, and reproducibility were conducted and the results are listed in Table 3 and Table 4 and in the Repeatability section.

Specificity

Table 3. Specificity of VENTANA anti-CD10 (SP67) was determined by testing formalin-fixed, paraffin-embedded normal tissues^a.

Tissues	# positive / total cases	Tissues	# positive / total cases
Cerebrum ^b	0/3	Thymus ^b	0/3
Cerebellum	0/3	Bone marrow	1/3
Adrenal gland ^b	1/3	Mesothelium of lung	3/6
Ovary	0/3	Lung	3/3
Pancreas ^b	0/3	Heart	0/3
Lymph node	2/3	Esophagus	0/3
Parathyroid gland	3/3	Stomach	0/3
Hypophysis (pituitary) ^b	0/3	Small intestine	3/3
Testis ^c	0/3	Colon ^b	0/3
Thyroid	0/3	Liver	3/3
Breast	3/3	Salivary gland	3/3
Spleen ^b	2/3	Kidney	3/3
Tonsil	3/3	Prostate	3/3
Endometrium	3/4	Cervix ^b	0/3
Skeletal muscle	4/4	Skin	0/3
Peripheral nerve	2/3	Bladder	3/3

^a positive cases show normal staining of one or more of the following structures: brush border, myoepithelial cells, pulmonary alveolar cells, bile canaliculi, proximal tubules, glomeruli, prostate glandular cells, and germinal center derived lymphocytes

^b staining of endothelial cells and lymphocytes

^c focal nuclear staining of the spermatogenic cells

Sensitivity

Table 4. Sensitivity of VENTANA anti-CD10 (SP67) was determined by testing a variety of formalin-fixed, paraffin-embedded neoplastic tissues.

Pathology	# positive / total cases
Glioblastoma with necrosis	1/1
Atypical meningioma	0/1
Malignant ependymoma	0/1
Oligodendroglioma	0/1
Ovarian serous adenocarcinoma	0/1
Ovarian adenocarcinoma	0/1
Islet cell tumor	1/1
Pancreatic adenocarcinoma	0/1
Seminoma	0/1
Seminoma with vascular tumor thrombus (sparse)	0/1
Thyroid medullary carcinoma	0/1
Thyroid papillary carcinoma	1/1
Invasive ductal carcinoma	0/3
Lung small cell undifferentiated carcinoma	0/1
Lung squamous cell carcinoma	1/1
Lung adenocarcinoma	0/1
Esophageal neuroendocrine carcinoma	0/1
Esophageal adenocarcinoma	0/1
Stomach signet-ring cell carcinoma	0/1
Small intestine adenocarcinoma	0/1
Small intestine stromal sarcoma	0/1
Colon adenocarcinoma	0/1
Peritoneum interstitialoma	0/1
Adenocarcinoma (rectum)	0/1
Rectum moderate malignant interstitialoma	0/1
Hepatocellular carcinoma	0/1
Hepatoblastoma	0/1
Renal clear cell carcinoma	52/56
Adenocarcinoma (Gleason grade:4; Gleason score:4+5) (prostate)	1/1
Adenocarcinoma (Gleason grade:3; Gleason score:3+4) (prostate)	1/1
Uterus leiomyoma	0/1
Uterus adenocarcinoma	0/1
Uterus clear cell carcinoma	0/1
Cervix squamous cell carcinoma	0/2

Pathology	# positive / total cases
Embryonal rhabdomyosarcoma	0/1
Malignant melanoma (rectum)	0/1
Basal cell carcinoma	0/1
Skin squamous cell carcinoma	0/1
Malignant mesothelioma	1/1
Bladder transitional cell carcinoma	1/1
Low grade malignant leiomyosarcoma	0/1
Osteosarcoma (sparse)	0/1
Spindle cell rhabdomyosarcoma	0/1
Moderate malignant leiomyosarcoma	0/1
Diffuse large B-cell lymphoma	37/98
Hodgkin lymphoma	0/3
B cell lymphoma not otherwise specified	4/30
Marginal zone lymphoma of mucosa associated tissue (MALT)	1/3
Mantle cell lymphoma	3/9
Anaplastic large cell lymphoma	0/1
Small lymphocytic lymphoma	1/1
T cell lymphoma	3/13
Renal papillary carcinoma	3/7
Kidney adenocarcinoma	0/1
Urothelial carcinoma	9/13
Oncocytoma	0/2
Chromophobe RCC	1/8
Eosinophilic variant of chromophobe renal cell carcinoma	1/1
Kidney squamous cell carcinoma	2/4
Kidney medullary carcinoma	0/1
NOS undifferentiated carcinoma	1/1
Nephroblastoma	2/3
Burkitt lymphoma	1/1

Repeatability

Repeatability studies for VENTANA anti-CD10 (SP67) were completed to demonstrate:

- Inter-lot reproducibility of the antibody.
- Intra-run and Inter-run reproducibility on a BenchMark XT instrument.
- Intra-platform reproducibility on the BenchMark XT instrument, BenchMark GX instrument and the BenchMark ULTRA instrument.
- Inter-platform reproducibility between the BenchMark XT instrument, BenchMark GX instrument and BenchMark ULTRA instrument.

All studies met their acceptance criteria.

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