

## VENTANA anti-CD10 (SP67) Rabbit Monoclonal Primary Antibody

**REF** 790-4506  
05857856001

**IVD**  50

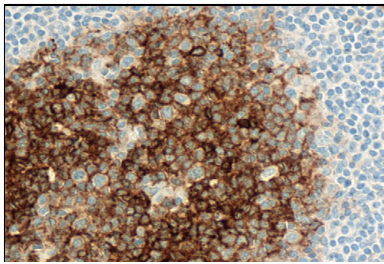


Figure 1. VENTANA anti-CD10 (SP67) membrane and/or cytoplasmic staining of Lymphoma.

### 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.<sup>1</sup> 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.<sup>2,3</sup> CD10 is expressed in a variety of normal tissue types, including early lymphoid cells, and various leukemias and lymphomas.<sup>4</sup> 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's lymphoma, in which CD10 is frequently expressed.<sup>5</sup> 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.<sup>6</sup>

### 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 SP67 antibody.

The antibody is diluted in phosphate buffered saline containing carrier protein and 0.05% ProClin 300, 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 rabbit recombinant monoclonal antibody produced as 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 (*ultraView* 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 BenchMark Series automated slide stainer. The recommended tissue fixative is 10% neutral buffered formalin.<sup>7</sup> 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. ProClin 300 is used as a preservative in this solution. 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.
3. Materials of human or animal origin should be handled as biohazardous materials and disposed of with proper precautions.
4. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
5. Avoid microbial contamination of reagents as it may cause incorrect results.
6. 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 BenchMark Series automated slide stainer in combination with Ventana detection kits and accessories. A recommended staining protocol for the BenchMark XT and BenchMark ULTRA instrument with *ultraView* Universal DAB Detection Kit is 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 kit package insert for more details regarding immunohistochemistry staining procedures.

Table 1. Recommended Staining Protocol for VENTANA anti-CD10 (SP67) with *ultraView* Universal DAB Detection Kit on a BenchMark XT and BenchMark ULTRA instrument.

Procedure Type	Method
Deparaffinization	Selected
Cell Conditioning (Antigen Unmasking)	Extended Cell Conditioning 1
Enzyme (Protease)	None Required
Antibody (Primary)	BenchMark XT instrument Approximately 16 Minutes, 37°C BenchMark ULTRA instrument Approximately 20 minutes, 36°C
Amplification*	Selected
Counterstain	Hematoxylin II, 4 Minutes
Post Counterstain	Bluing, 4 Minutes

\* Amplification Kit (REF 760-080)

Table 2. Recommended staining protocol for VENTANA anti-CD10 (SP67) with *View* DAB Detection Kit on a BenchMark XT instrument.

Procedure Type	Method
Deparaffinization	Selected
Cell Conditioning (Antigen Unmasking)	Extended Cell Conditioning 1
Enzyme (Protease)	None Required
Antibody (Primary)	BenchMark XT instrument Approximately 32 Minutes, 37°C
Amplification*	Selected
Counterstain	Hematoxylin II, 4 Minutes
Post Counterstain	Bluing, 4 Minutes

\* 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."<sup>8</sup>

### POSITIVE TISSUE CONTROL

An example of positive control tissue for this antibody is tonsil. In tonsil, B cells in the germinal centers stain positive along with scattered lymphocytes.

### STAINING INTERPRETATION

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

### SPECIFIC LIMITATIONS

This antibody has been optimized with Extended Cell Conditioning 1 and a 16 minute primary antibody incubation time on a BenchMark XT instrument and Extended Cell Conditioning 1 with a 20 minute primary antibody incubation time on a BenchMark ULTRA instrument in combination with *ultraView* Universal DAB Detection Kit and an Amplification Kit (REF 760-080) but the user must validate results obtained with this reagent.

### PERFORMANCE CHARACTERISTICS

Staining tests for specificity, sensitivity, and reproducibility were conducted using VENTANA anti-CD10 (SP67) with *ultraView* Universal DAB Detection Kit on BenchMark XT and BenchMark ULTRA instruments.

### Specificity

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

Tissues	# positive / total cases	Tissues	# positive / total cases
Cerebrum	0/3	Thymus	0/3
Cerebellum	0/3	Myeloid (bone marrow)	2/3
Adrenal gland	0/3	Lung	3/3
Ovary	0/3	Heart	0/3
Pancreas	0/3	Esophagus	0/3
Parathyroid gland	0/3	Stomach	0/3
Hypophysis	0/3	Small intestine	3/3
Testis	0/3	Colon	1/3
Thyroid	0/3	Liver	3/3
Breast	3/3	Salivary gland	3/3
Spleen	3/3	Kidney	8/8
Tonsil	3/3	Prostate	3/3
Endometrium	3/3	Cervix	0/3
Skeletal muscle	0/3	Skin	0/3
Nerve (sparse)	2/3	Mesothelium and lung	0/3

### 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	0/1
Atypical meningioma	0/1
Malignant ependymoma	0/1
Malignant oligodendroglioma	0/1
Serous papillary adenocarcinoma	0/1
Mucinous papillary adenocarcinoma	0/1
Islet cell carcinoma	1/1
Pancreatic adenocarcinoma	0/1
Seminoma	0/1
Embryonal carcinoma	0/1
Medullary carcinoma	0/1
Papillary carcinoma	0/1
Breast intraductal carcinoma	0/1
Breast lobular carcinoma <i>in situ</i>	0/1
Breast invasive ductal carcinoma	0/1
Diffuse B-cell lymphoma	15/56
Lung small cell undifferentiated carcinoma	0/1

Pathology	# positive / total cases
Lung squamous cell carcinoma	0/1
Lung adenocarcinoma	0/1
Esophageal squamous cell carcinoma	0/1
Esophageal adenocarcinoma	0/1
Gastric mucinous adenocarcinoma	0/1
Gastrointestinal adenocarcinoma	0/1
GIST	0/1
Colon adenocarcinoma	0/1
Colon intermediate grade interstitialoma	0/1
Rectal adenocarcinoma	0/1
Rectal intermediate grade interstitialoma	0/1
Hepatocellular carcinoma	0/1
Hepatoblastoma	0/1
Renal clear cell carcinoma	41/42
Granular cell carcinoma	9/11
Transitional cell carcinoma	6/6
Granular clear cell carcinoma	7/7
Chromophobe carcinoma	1/2
Papillary Carcinoma	1/2
Kidney squamous cell carcinoma	0/1
Cancer adjacent normal renal tissue	5/5
Prostatic adenocarcinoma	1/1
Prostatic transitional cell carcinoma	1/1
Leiomyoma	0/1
Endometrial adenocarcinoma	0/1
Endometrial clear cell carcinoma	0/1
Uterine squamous cell carcinoma	1/2
Embryonal rhabdomyosarcoma	0/1
Anal malignant melanoma	0/1
Basal cell carcinoma	0/1
Squamous cell carcinoma	0/1
Neurofibroma	1/1
Retroperitoneal neuroblastoma	0/1
Epithelial malignant mesothelioma	1/1
T Cell Lymphoma	2/5
Mucosa Associated Lymphoma	0/3
Follicular Lymphoma	3/6
Mantle Cell Lymphoma	0/1
Burkitt's Lymphoma	8/8

Pathology	# positive / total cases
Burkitt's Like Lymphoma	0/1
Myeloma	4/10
Lymphocytic Plasmacytoid Lymphoma	1/2
Hodgkin's lymphoma	0/10
Diffuse malignant lymphoma	3/3
Bladder transitional cell carcinoma	1/1
Low grade leiomyosarcoma	0/1
Osteosarcoma	0/1
Spindle cell rhabdomyosarcoma	0/1
Intermediate grade leiomyosarcoma	0/1

### Precision

Precision 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 and the BenchMark ULTRA instrument.
- Inter-platform reproducibility between the BenchMark XT and BenchMark ULTRA instruments.

### Compatibility Results

VENTANA anti-CD10 (SP67) demonstrated compatibility with Ventana BenchMark XT, and BenchMark ULTRA instruments and *View* DAB Detection Kit and *ultraView* Universal DAB Detection Kit.

### REFERENCES

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