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

REF 790-4506

05857856001

IVD Σ 50

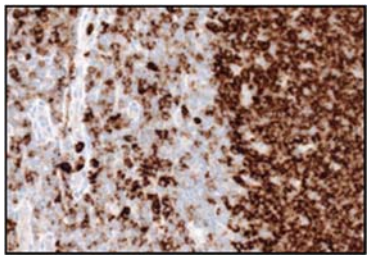

Figure 1. VENTANA anti-CD10 (SP67) antibody exhibiting a membrane and/or cytoplasmic staining pattern in lymphoma tissue.

## INTENDED USE

VENTANA anti-CD10 (SP67) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD10 by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument.

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) Rabbit Monoclonal Primary Antibody (VENTANA anti-CD10 (SP67) antibody) is a recombinant rabbit monoclonal antibody. CD10, or the common acute lymphoblastic leukemia antigen (CALLA), is a 90- to 110-kDa integral membrane glycoprotein.[1-4] As a peptidase, CD10 cleaves various substrates, lowers the extracellular concentrations of the substrates, and alters downstream signaling mechanisms.[2,3] In the hematopoietic system, CD10 is normally expressed in early lymphoid cells, detected transiently during B-cell differentiation, especially in germinal center B-cells (GCB), but its expression is lost in mature B-cells.[1-5] Detection of CD10 is useful in the characterization of a subset of malignant lymphomas, including B-cell acute lymphoblastic leukemia (B-ALL), and neoplasms derived from GCB such as diffuse large B-cell lymphoma, follicular lymphoma, and Burkitt lymphoma.[1-4] Aside from B-cells, CD10 is also normally expressed in non-hematopoietic tissues such as the prostate, kidneys, intestines, and lungs.[6,7,8] In particular, CD10 has been a useful marker to aid in the identification of some renal cell carcinomas such as clear cell renal cell carcinoma and papillary renal cell carcinoma.[6,7,8]

The detection of CD10 by immunohistochemistry (IHC) with VENTANA anti-CD10 (SP67) antibody may be used in the detection of CD10-positive B-cells to aid in the identification of B-acute lymphoblastic leukemia (B-ALL) and neoplasms derived from germinal center B-cell (GCB) origins and the detection of renal cells to aid in the classification of some renal cell carcinomas. This antibody may be used as part of a panel of IHC studies. The staining pattern is membranous and/or cytoplasmic.

## PRINCIPLE OF THE PROCEDURE

VENTANA anti-CD10 (SP67) antibody is a rabbit monoclonal antibody produced against a synthetic peptide corresponding to the human CD10 protein. VENTANA anti-CD10 (SP67) antibody binds to the CD10 protein in formalin-fixed, paraffin-embedded (FFPE) 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 respective method sheet for further information.

## MATERIAL PROVIDED

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

One 5 mL dispenser of VENTANA anti-CD10 (SP67) antibody 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.

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) antibody is a recombinant monoclonal antibody produced from purified cell culture supernatant.

Refer to the appropriate VENTANA detection kit method sheet for detailed descriptions of: Principle of the Procedure, Material and Methods, Specimen Collection and Preparation for Analysis, Quality Control Procedures, Troubleshooting, Interpretation of Results, and 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 method sheet may be available in all geographies. Consult your local support representative.

The following reagents and materials may be required for staining but are not provided:

1. Recommended control tissue
2. Microscope slides, positively charged
3. Rabbit Monoclonal Negative Control Ig (Cat. No. 790-4795 / 06683380001)
4. OptiView DAB IHC Detection Kit (Cat. No. 760-700 / 06396500001)
5. *ultra*View Universal DAB Detection Kit (Cat. No. 760-500 / 05269806001)
6. OptiView Amplification Kit (Cat. No. 760-099 / 0639518001)
7. Amplification Kit (Cat. No. 760-080 / 05266114001)
8. EZ Prep Concentrate (10X) (Cat. No. 950-102 / 05279771001)
9. Reaction Buffer Concentrate (10X) (Cat. No. 950-300 / 05353955001)
10. LCS (Predilute) (Cat. No. 650-010 / 05264839001)
11. ULTRA LCS (Predilute) (Cat. No. 650-210 / 05424534001)
12. Cell Conditioning Solution (CC1) (Cat. No. 950-124 / 05279801001)
13. ULTRA Cell Conditioning Solution (ULTRA CC1) (Cat. No. 950-224 / 05424569001)
14. Hematoxylin II (Cat. No. 790-2208 / 05277965001)
15. Bluing Reagent (Cat. No. 760-2037 / 05266769001)
16. Permanent mounting medium
17. Cover glass
18. Automated coverslipper
19. General purpose laboratory equipment
20. BenchMark IHC/ISH instrument

## STORAGE AND STABILITY

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 FFPE tissues are suitable for use with this primary antibody when used with VENTANA detection kits and a BenchMark IHC/ISH instruments. The recommended tissue fixative is 10% neutral buffered formalin.[9] Sections should be cut at approximately 4 µm in thickness and mounted on positively charged slides. Slides should be stained immediately, as antigenicity of cut tissue sections may diminish over time. Ask your Roche representative for a copy of "Recommended Slide Storage and Handling" for more information.

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. CAUTION: In the United States, Federal law restricts this device to sale by or on the order of a physician. (Rx Only)
4. Do not use beyond the specified number of tests.
5. 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.

6. Positively charged slides may be susceptible to environmental stresses resulting in inappropriate staining. Ask your Roche representative for more information on how to use these types of slides.
7. Materials of human or animal origin should be handled as biohazardous materials and disposed of with proper precautions. In the event of exposure, the health directives of the responsible authorities should be followed.[10,11]
8. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
9. Avoid microbial contamination of reagents as it may cause incorrect results.
10. For further information on the use of this device, refer to the BenchMark IHC/ISH instrument User Guide, and instructions for use of all necessary components located at dialog.roche.com.
11. Consult local and/or state authorities with regard to recommended method of disposal.
12. Product safety labeling primarily follows EU GHS guidance. Safety data sheet available for professional user on request.
13. To report suspected serious incidents related to this device, contact the local Roche representative and the competent authority of the Member State or Country in which the user is established.

This product contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Table 1. Hazard information.

| Hazard | Code | Statement |
|---|---|---|
| Warning  | H317 | May cause an allergic skin reaction. |
| | P261 | Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray. |
| | P272 | Contaminated work clothing should not be allowed out of the workplace. |
| | P280 | Wear protective gloves. |
| | P333 + P313 | If skin irritation or rash occurs: Get medical advice/ attention. |
| | P362 + P364 | Take off contaminated clothing and wash it before reuse. |
| | P501 | Dispose of contents/ container to an approved waste disposal plant. |

This product contains CAS # 55965-84-9, reaction mass of: 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1).

## 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 the tables below 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 instrument User Guide. Refer to the appropriate VENTANA detection kit method sheet for more details regarding immunohistochemistry staining procedures.

For more details on the proper use of this device, refer to the inline dispenser method sheet associated with P/N 790-4506.

Table 2. Recommended staining protocol for VENTANA anti-CD10 (SP67) antibody with OptiView DAB IHC Detection Kit on BenchMark IHC/ISH instruments.

| Procedure Type | Method | | |
|---|---|---|---|
| | GX | XT | ULTRA or ULTRA PLUS [a] |
| Deparaffinization | Selected | Selected | Selected |
| Cell Conditioning (Antigen Unmasking) | CC1, 92 minutes | CC1, 92 minutes | ULTRA CC1, 92 minutes, 100°C |
| Pre-Primary Peroxidase Inhibitor | Selected | Selected | Selected |
| Antibody (Primary) | 32 minutes, 37°C | 12 minutes, 37°C | 28 minutes, 36°C |
| OptiView HQ Linker | 8 minutes (default) | | |
| OptiView HRP Multimer | 8 minutes (default) | | |
| OV AMP H2O2, OV Amplifier | 8 minutes | 12 minutes | 8 minutes |
| OV AMP Multimer | 8 minutes | 12 minutes | 8 minutes |
| Counterstain | Hematoxylin II, 4 minutes | | |
| Post Counterstain | Bluing, 4 minutes | | |

[a] Concordance was demonstrated between BenchMark ULTRA and BenchMark ULTRA PLUS instruments using representative assays.

Table 3. Recommended staining protocol for VENTANA anti-CD10 (SP67) antibody *ultra*View Universal DAB Detection Kit on BenchMark IHC/ISH instruments.

| Procedure Type | Method | | |
|---|---|---|---|
| | GX | XT | ULTRA or ULTRA PLUS [a] |
| Deparaffinization | Selected | Selected | Selected |
| Cell Conditioning (Antigen Unmasking) | CC1 Extended | CC1 Extended | ULTRA CC1 Extended |
| Antibody (Primary) | 28 minutes, 37°C | 16 minutes, 37°C | 20 minutes, 36°C |
| Amplification | Selected | Selected | Selected (Rabbit) |
| Counterstain | Hematoxylin II, 4 minutes | | |
| Post Counterstain | Bluing, 4 minutes | | |

[a] Concordance was demonstrated between BenchMark ULTRA and BenchMark ULTRA PLUS instruments using representative assays.

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."[12]

## NEGATIVE REAGENT CONTROL

In addition to staining with VENTANA anti-CD10 (SP67) antibody, a second slide should be stained with the appropriate negative control reagent.

## POSITIVE TISSUE CONTROL

Optimal laboratory practice is to include a positive control section on the same slide as the test tissue. This helps identify any failures applying reagents to the slide. Tissue with weak positive staining is best suited for quality control. Control tissue may contain both positive

and negative staining elements and serve as both the positive and negative control. Control tissue should be fresh autopsy, biopsy, or surgical specimen, prepared or fixed as soon as possible in a manner identical to test sections.

Known positive tissue controls should be utilized only for monitoring performance of reagents and instruments, not as an aid in determining specific diagnosis of test samples. If the positive tissue controls fail to demonstrate positive staining, results of the test specimen should be considered invalid.

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) antibody is membranous and/or cytoplasmic.

## SPECIFIC LIMITATIONS

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

All assays might not be registered on every instrument. Please contact your local Roche representative for more information.

## PERFORMANCE CHARACTERISTICS

## ANALYTICAL PERFORMANCE

Staining tests for specificity, sensitivity, and precision were conducted and the results are listed below.

### Sensitivity and Specificity

Staining was observed in many normal structures including: myoepithelial cells of the breast and salivary glands, stromal cells of the ovary and uterus, pulmonary alveolar cells, bile canaliculi, renal proximal tubules and glomeruli, prostate glandular cells, mesothelium, nerve cells and the brush border of the small intestines. These cases are all considered positive as specific elements of these tissue types showed staining.

Staining of endothelial cells and lymphocytes is also present in many normal tissues, however these cases (called out in the footnote) are all considered negative because staining was not observed in specific elements of that tissue type.

Table 4. Sensitivity/Specificity of VENTANA anti-CD10 (SP67) antibody was determined by testing FFPE normal tissues.

| Tissues | # positive / total cases | Tissues | # positive / total cases |
|---|---|---|---|
| Cerebrum [a] | 0/3 | Esophagus [a] | 0/3 |
| Cerebellum | 0/3 | Stomach [a] | 0/3 |
| Adrenal gland [a] | 1/3 | Small intestine | 3/3 |
| Ovary [b] | 0/3 | Colon [a] | 0/3 |
| Pancreas [b] | 0/3 | Liver | 3/3 |
| Lymph node [c] | 3/4 | Salivary gland | 3/3 |
| Parathyroid gland [a, b] | 3/3 | Nasopharynx [c] | 0/1 |
| Pituitary gland [a] | 0/3 | Kidney [b, c] | 6/7 |
| Testis | 0/3 | Prostate | 3/3 |
| Thyroid | 0/3 | Bladder [b] | 3/3 |
| Breast | 3/3 | Endometrium | 3/3 |
| Spleen [c] | 3/4 | Cervix [a] | 0/3 |
| Tonsil [c] | 4/4 | Skeletal muscle [b] | 0/4 |
| Thymus [a, b] | 0/3 | Skin | 0/3 |
| Bone marrow | 1/3 | Nerve | 2/3 |
| Lung | 3/3 | Mesothelium | 3/6 |
| Heart | 0/3 | | |

[a] Lymphocytes were staining positive in some or all cases but case positivity was not based on lymphocyte staining.

[b] Endothelial cells were staining positive in some or all cases but case positivity was not based on endothelial cell staining.

[c] Tissues evaluated include normal and chronic inflammation.

Table 5. Sensitivity/Specificity of VENTANA anti-CD10 (SP67) antibody was determined by testing a variety of FFPE neoplastic tissues.

| Pathology | # positive / total cases |
|---|---|
| Glioblastoma (Cerebrum) | 1/1 |
| Meningioma (Cerebrum) | 0/1 |
| Ependymoma (Cerebrum) | 0/1 |
| Oligodendroglioma (Cerebrum) | 0/1 |
| Serous adenocarcinoma (Ovary) | 0/1 |
| Adenocarcinoma (Ovary) | 0/1 |
| Neuroendocrine neoplasm (Pancreas) | 1/1 |
| Adenocarcinoma (Pancreas) | 0/1 |
| Seminoma (Testis) | 0/2 |
| Medullary carcinoma (Thyroid) | 0/1 |
| Papillary carcinoma (Thyroid) | 1/1 |
| Invasive ductal carcinoma (Breast) | 1/3 |
| Small cell carcinoma (Lung) | 0/1 |
| Squamous cell carcinoma (Lung) | 1/1 |
| Adenocarcinoma (Lung) | 0/1 |
| Neuroendocrine carcinoma (Esophagus) | 0/1 |
| Adenocarcinoma (Esophagus)i | 0/1 |
| Signet-ring cell carcinoma (Stomach) | 0/1 |
| Adenocarcinoma (Small intestine) | 0/1 |
| Stromal sarcoma (Small intestine) | 0/1 |
| Adenocarcinoma (Colon) | 0/1 |
| Gastrointestinal stromal tumor (GIST) (Colon) | 0/1 |
| Adenocarcinoma (Rectum) | 0/1 |
| Gastrointestinal stromal tumor (GIST) (Rectum) | 0/1 |
| Melanoma (Rectum) | 0/1 |
| Hepatocellular carcinoma (Liver) | 0/1 |

| Pathology | # positive / total cases |
|---|---|
| Hepatoblastoma (Liver) | 0/1 |
| Clear cell carcinoma (Kidney) | 50/55 |
| Papillary carcinoma (Kidney) [a] | 3/7 |
| Adenocarcinoma (Kidney) [a] | 0/1 |
| Urothelial carcinoma (Kidney) | 9/13 |
| Oncocytoma (Kidney) | 0/2 |
| Chromophobe renal cell carcinoma (Kidney) | 1/8 |
| Chromophobe renal cell carcinoma, eosinophilic variant (Kidney) | 1/1 |
| Squamous cell carcinoma (Kidney) [a] | 2/4 |
| Medullary carcinoma (Kidney) | 0/1 |
| Carcinoma, NOS (Kidney) | 1/1 |
| Nephroblastoma (Kidney) | 2/3 |
| Adenocarcinoma (Prostate) | 2/2 |
| Leiomyoma (Uterus) | 0/1 |
| Adenocarcinoma (Uterus) | 0/1 |
| Clear cell carcinoma (Uterus) | 0/1 |
| Squamous cell carcinoma (Cervix) | 0/2 |
| Embryonal rhabdomyosarcoma (Striated muscle) | 0/1 |
| Basal cell carcinoma (Skin) | 0/1 |
| Squamous cell carcinoma (Skin) | 0/1 |
| Mesothelioma (Peritoneum) | 1/1 |
| Spindle cell rhabdomyosarcoma (Retroperitoneum) | 0/1 |
| Hodgkin lymphoma (Lymph node) | 0/3 |
| Angioimmunoblastic T-cell lymphoma | 1/5 |
| Peripheral T-cell lymphoma | 1/3 |
| Anaplastic large cell lymphoma | 0/1 |
| T cell lymphoma, NOS | 1/4 |
| MALT B-cell lymphoma | 1/7 |
| Extranodal marginal zone B-cell lymphoma | 0/1 |
| Mantle cell lymphoma | 3/9 |
| Burkitt lymphoma | 1/1 |
| Follicular lymphoma | 9/9 |
| Diffuse large B-cell lymphoma (DLBCL) | 36/94 |
| B cell lymphoma NOS [a] | 5/27 |
| Small lymphocytic lymphoma/chronic lymphocytic leukemia | 1/3 |
| T lymphoblastic lymphoma | 0/1 |
| Urothelial carcinoma (Bladder) | 1/1 |
| Leiomyosarcoma (Bladder) | 0/1 |
| Osteosarcoma (Bone) | 0/1 |
| Leiomyosarcoma (Smooth muscle) | 0/1 |

[a] Normal lymphocytes were staining positive in some or all cases but case positivity was based on neoplastic cell staining.

### Precision

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

- Between lot precision of the antibody.
- Within run and between day precision on a BenchMark XT instrument.
- Between instrument precision on the BenchMark GX, BenchMark XT, and BenchMark ULTRA instruments.
- Between platform precision between the BenchMark GX, BenchMark XT, and BenchMark ULTRA instruments.

All studies met their acceptance criteria.

Precision on the BenchMark ULTRA PLUS instrument was demonstrated using representative assays. Studies included Within-run Repeatability, Between-day and Between-run Intermediate Precision. All studies met their acceptance criteria.

## CLINICAL PERFORMANCE

Clinical performance data relevant for the intended purpose of VENTANA anti-CD10 (SP67) antibody were assessed by systematic review of the literature. The data gathered support the use of the device in accordance with its intended purpose.

## REFERENCES


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NOTE: A point (period/stop) is always used in this document as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

The summary of safety and performance can be found here:

https://ec.europa.eu/tools/eudamed

### Symbols

Ventana uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.roche.com for definition of symbols used):

| | |
|---|---|
| GTIN | Global Trade Item Number |
| UDI | Unique Device Identification |
|  | Indicates the entity importing the medical device into the European Union |

### REVISION HISTORY

| Rev | Updates |
|---|---|
| H | Updates to Principle of Procedure, Specimen Preparation, Warnings and Precautions, Staining Procedure, Negative Reagent Control, Analytical Performance and Symbols sections. Added BenchMark ULTRA PLUS instrument |

### INTELLECTUAL PROPERTY



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