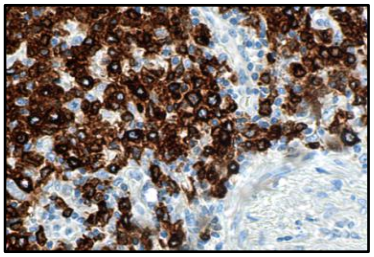
CONFIRM anti-CD79a (SP18) Rabbit Monoclonal Primary Antibody

REF 790-4432

05640296001

IVD Σ 50



CONFIRM anti-CD79a (SP18) antibody staining of MALT lymphoma in the thyroid

INTENDED USE

CONFIRM anti-CD79a (SP18) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD79a 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

CONFIRM anti-CD79a (SP18) Rabbit Monoclonal Primary Antibody (CONFIRM anti-CD79a (SP18) antibody) was raised against the CD79a protein. CD79a is a heterodimeric transmembrane protein that is expressed on the surface of B cells at all stages of maturation.[1,2] CD79a is responsible for presenting the IgM molecule to the extracellular matrix.[1,2] The intracellular domain of the CD79a protein contains an immunoreceptor tyrosine-based activation motif (ITAM) domain that propagates downstream signaling and drives differentiation of B cells.[1,2] CD79a is present on both the plasma membrane and the cytoplasm of B cells.[1,2,3] The expression of CD79a is largely restricted to the B cell lineage, making it a robust marker for neoplastic and normal tissues of this classification.[2,3] However, CD79a has been observed in acute myeloid leukemias, myelomas, and some T cell lymphomas.[4,5]

The detection of CD79a by immunohistochemistry (IHC) with the CONFIRM anti-CD79a (SP18) antibody may be used to aid in the identification of normal and neoplastic B cells. 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

CONFIRM anti-CD79a (SP18) antibody binds to CD79a protein in formalin-fixed, paraffin-embedded (FFPE) tissue sections. 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 *ultra*View Universal DAB Detection Kit or OptiView DAB IHC Detection Kit method sheet for further information.

MATERIAL PROVIDED

CONFIRM anti-CD79a (SP18) antibody contains sufficient reagent for 50 tests.

One 5 mL dispenser of CONFIRM anti-CD79a (SP18) antibody contains approximately 1.5 µg of a rabbit monoclonal antibody.

The antibody is diluted in Phosphate Buffer with carrier proteins and 0.10% ProClin 300, a preservative.

Specific antibody concentration is approximately 0.3 µg/mL. There is no known non-specific antibody reactivity observed in this product.

CONFIRM anti-CD79a (SP18) antibody is a recombinant rabbit monoclonal antibody produced as 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. EZ Prep Concentrate (10X) (Cat. No. 950-102 / 05279771001)
7. Reaction Buffer Concentrate (10X) (Cat. No. 950-300 / 05353955001)
8. LCS (Predilute) (Cat. No. 650-010 / 05264839001)
9. ULTRA LCS (Predilute) (Cat. No. 650-210 / 05424534001)
10. Cell Conditioning Solution (CC1) (Cat. No. 950-124 / 05279801001)
11. ULTRA Cell Conditioning Solution (ULTRA CC1) (Cat. No. 950-224 / 05424569001)
12. Hematoxylin II (Cat. No. 790-2208 / 05277965001)
13. Bluing Reagent (Cat. No. 760-2037 / 05266769001)
14. Permanent mounting medium
15. Cover glass
16. Automated coverslipper
17. General purpose laboratory equipment
18. 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 BenchMark IHC/ISH instruments. The recommended tissue fixative is 10% neutral buffered formalin.[6] 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.

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. Do not use beyond the specified number of tests.
4. 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.
5. 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.
6. 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.[7,8]
7. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
8. Avoid microbial contamination of reagents as it may cause incorrect results.
9. 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 navifyportal.roche.com.

10. Consult local and/or state authorities with regard to recommended method of disposal.
11. Product safety labeling primarily follows EU GHS guidance. Safety data sheet available for professional user on request.
12. 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 mist or vapors.
	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, a 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 790-4432.

Table 2. Recommended staining protocol for CONFIRM anti-CD79a (SP18) antibody with *ultra*View Universal DAB Detection Kit on BenchMark IHC/ISH instruments.

Procedure Type	Method	
	GX	ULTRA or ULTRA PLUS [a]
Deparaffinization	Selected	Selected
Cell Conditioning (Antigen Unmasking)	CC1, Standard	ULTRA CC1, Standard
Antibody (Primary)	16 minutes, 37°C	20 minutes, 36 °C
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 CONFIRM anti-CD79a (SP18) antibody with OptiView DAB IHC Detection Kit on BenchMark IHC/ISH instruments.

Procedure Type	Method	
	GX	ULTRA or ULTRA PLUS [a]
Deparaffinization	Selected	Selected
Cell Conditioning (Antigen Unmasking)	CC1, 48 minutes, 95 °C	ULTRA CC1, 48 minutes, 100 °C
Pre-Primary Peroxidase Inhibitor	Selected	Selected
Antibody (Primary)	16 minutes, 37°C	20 minutes, 36 °C
OptiView HQ Linker	8 minutes	
OptiView HRP Multimer	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.

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."[9]

NEGATIVE REAGENT CONTROL

In addition to staining with CONFIRM anti-CD79a (SP18) 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.

Examples of positive control tissues for this antibody are B cell lymphomas and tonsil.

STAINING INTERPRETATION / EXPECTED RESULTS

The cellular staining pattern for CONFIRM anti-CD79a (SP18) antibody is membranous and cytoplasmic.

SPECIFIC LIMITATIONS

OptiView detection system is generally more sensitive than *ultra*View. 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

Several tissues demonstrated staining of normal infiltrating B cells. Normal dendritic cells stained positively with CONFIRM anti-CD79a (SP18) antibody.

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

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Sensitivity and Specificity

Table 4. Sensitivity/Specificity of CONFIRM anti-CD79a (SP18) antibody was determined by testing FFPE normal tissues.

Tissue	# positive / total cases	Tissue	# positive / total cases
Cerebrum	0/3	Stomach [a]	0/4
Cerebellum	0/4	Small intestine [a]	0/4
Eye	0/2	Colon [a]	0/4
Adrenal gland	0/4	Rectum [a]	0/3
Ovary [a]	0/4	Liver [a]	0/4
Pancreas [a]	0/3	Salivary gland [a]	0/4
Lymph node	15/15	Kidney	0/6
Parathyroid gland [a]	0/3	Prostate [a]	0/4
Pituitary gland	0/3	Bladder [a]	0/4
Testis [a]	0/4	Ureter	0/2
Thyroid [a]	0/3	Placenta [a]	0/3
Breast [a]	0/4	Endometrium [a]	0/3
Spleen	3/3	Cervix [a]	0/3
Tonsil	3/3	Skeletal muscle	0/3
Thymus	3/3	Spinal Cord	0/2
Bone marrow	4/4	Skin [a]	0/3
Lung [a]	0/4	Nerve	0/3
Heart	0/3	Mesothelium [a]	0/6
Esophagus [a]	0/4		

[a] Normal B-cells/plasma cells staining

Table 5. Sensitivity/Specificity of CONFIRM anti-CD79a (SP18) antibody was determined by testing a variety of FFPE neoplastic tissues.

Pathology	# positive / total cases
Astrocytoma (Cerebrum)	0/1
Meningioma, fibroblastic (Cerebrum)	0/1
Meningioma, fibroblastic (Cerebellum)	0/1
Malignant Meningioma (Cerebellum)	0/1
Adenoma, cortical (Adrenal Gland)	0/1
Adrenocortical Carcinoma (Adrenal Gland)	0/1
Adenocarcinoma (Head and neck)	0/1
Squamous cell carcinoma (Head and neck)	0/1
Nasopharyngeal carcinoma (Head and neck)	0/1
Melanoma (Head and neck)	0/1
Granulosa cell tumor (Ovary)	0/1
Adenocarcinoma (Ovary)	0/1
Endometroid adenocarcinoma (Ovary)	0/1
Metastatic colon signet ring cell carcinoma (Ovary)	0/1
Adenocarcinoma (Pancreas)	0/1
Seminoma (Testis)	0/2
Adenoma (Thyroid)	0/3
Follicular carcinoma (Thyroid)	0/1
Follicular Papillary carcinoma (Thyroid)	0/1
Fibroadenoma (Breast)	0/2
Invasive ductal carcinoma (Breast)	0/3
Squamous cell carcinoma (Lung)	0/2
Adenocarcinoma (Lung)	0/1
Small cell carcinoma (Lung)	0/1
Metastatic Cancer (Lung)	0/1
Squamous cell carcinoma (Esophagus)	0/3
Adenocarcinoma (Stomach)	0/2
Adenoma (Small intestine)	0/1
Adenocarcinoma (Small intestine)	0/1
Adenoma (Intestine, colon)	0/1
Adenocarcinoma (Intestine, colon)	0/3
Adenocarcinoma (Intestine, rectum)	0/3
Hepatocellular carcinoma (Liver)	0/4
Metastatic colon adenocarcinoma (Liver)	0/1
Clear cell carcinoma (Kidney)	0/2
Adenocarcinoma (Prostate)	0/2
Adenocarcinoma (Uterus)	0/2
Squamous cell carcinoma (Cervix)	0/2
Squamous cell carcinoma (Skin)	0/1
Osteosarcoma (Bone)	0/1
Metastatic breast invasive ductal carcinoma (Lymph node)	0/1
Metastatic esophagus squamous cell carcinoma (Lymph node)	0/1
Transitional cell carcinoma (Bladder)	0/2
Pleomorphic adenoma (Salivary gland)	0/1
Adenoid cystic carcinoma (Salivary gland)	0/1
Hodgkin Lymphoma	1/12
Angioimmunoblastic T-cell Lymphoma	0/4
Peripheral T-cell Lymphoma	1/1
Peripheral T-cell Lymphoma-lymphoepithelioid variant	0/1
T-cell lymphoma, NOS	11/19
Anaplastic large cell lymphoma [a]	6/7
Nodal marginal zone B-cell lymphoma	1/1
Mantle cell lymphoma	12/12
Burkitt lymphoma	3/3
Follicular lymphoma	5/5
Diffuse large B-cell lymphoma (DLBCL)	26/27
Small lymphocytic lymphoma/chronic lymphocytic leukemia	18/18

Pathology	# positive / total cases
B-cell Lymphoma, NOS	72/75
T-cell lymphoblastic lymphoma	0/1
Plasma cell neoplasm	9/10

[a] Staining noted in ALCL. Given the limited core, and positivity with multiple clones, these cores could reflect morphologic mimics of ALCL, such as DLBCL, anaplastic variant.

Precision

Precision studies for CONFIRM anti-CD79a (SP18) antibody were completed to demonstrate:

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

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-Instrument Intermediate Precision. All studies met their acceptance criteria.

CLINICAL PERFORMANCE

Clinical performance data relevant for the intended purpose of CONFIRM anti-CD79a (SP18) 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 elabdoc.roche.com/symbols for more information).

GTIN	Global Trade Item Number
Rx only	For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

REVISION HISTORY

Rev	Updates
F	Updates to Principle of the Procedure, Material Provided, Materials Required But Not Provided, Warnings and Precautions, Staining Procedure, Specific Limitations, Analytical Performance and Intellectual Property sections. Added GX, added OptiView DAB IHC Detection Kit, updated Sensitivity and Specificity tables, removed XT and added ULTRA PLUS to Precision. Used template from FT0700-410 Revision V.

INTELLECTUAL PROPERTY

For USA: Rx only

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