Anti-CD43 (L60) Mouse Monoclonal Primary Antibody

REF 760-2511

05266980001

IVD Σ 50

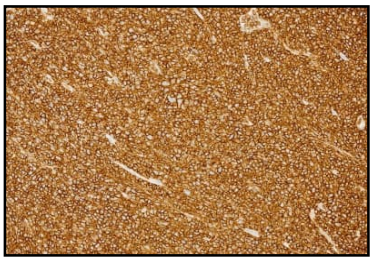

Figure 1. Anti-CD43 (L60) antibody staining in peripheral T-cell lymphoma.

INTENDED USE

Anti-CD43 (L60) Mouse Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of CD43 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

CD43, also known as leucosialin or sialophorin, is a transmembrane glycoprotein antigen expressed on the plasma membrane and in the cytoplasm of hematopoietic precursors, cells of myeloid origin except mature erythrocytes, and normal lymphoid cells including T cells, NK cells, precursor B cells, B cells in the gastrointestinal mucosa and plasma cells, but not resting peripheral B cells.[1,2] Western blotting demonstrates heterogeneity of the antigen staining bands in the 110-160 kD range. CD43 is expressed by most T cell lymphomas and some B cell lymphomas.[1-4] Anti-CD43 (L60) Mouse Monoclonal Primary Antibody (Anti-CD43 (L60) antibody) binds specifically to antigens located in the plasma membrane and cytoplasmic regions of normal granulocytes, monocytes, histiocytes, T cells, and some B cells.

CD43 is expressed by most T cell lymphomas.[1-4] When used in a panel with other T-cell markers, the detection of CD43 by immunohistochemistry (IHC) with the Anti-CD43 (L60) antibody may be used as an aid to diagnose T-cell lymphoma.

While normal mature B cells do not express CD43, some mature B-cell neoplasms (e.g., small lymphocytic lymphoma and mantle cell lymphoma) often express it aberrantly.[1-4] Thus, detection of CD43 by IHC with the Anti-CD43 (L60) antibody may also be used as an aid to characterize B-cell lymphoma. CD43 IHC is mostly used to characterize small B-cell lymphomas. CD43 positivity is highest among chronic lymphocytic leukemia/small lymphocytic lymphoma and mantle cell lymphoma, and is almost always absent in follicular lymphoma.[1,2] Its use to characterize other B-cell lymphoma subtypes is more limited.[1,2]

The staining pattern of this antibody is membranous and cytoplasmic. It may be used as part of a panel of IHC studies.

PRINCIPLE OF THE PROCEDURE

Anti-CD43 (L60) antibody binds to the CD43 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), and *ultra*View Universal DAB Detection Kit (Cat. No. 760-500 / 05269806001). Refer to the respective method sheets for further information.

MATERIAL PROVIDED

Anti-CD43 (L60) antibody contains sufficient reagent for 50 tests.

One 5 mL dispenser of Anti-CD43 (L60) antibody contains approximately 5 µg of a mouse monoclonal antibody.

The antibody is diluted in phosphate buffered saline containing carrier protein and 0.10% ProClin 300, a preservative.

Specific antibody concentration is approximately 1 µg/mL. There is no known non-specific antibody reactivity observed in this product.

Anti-CD43 (L60) antibody is a mouse monoclonal antibody produced as tissue culture supernatant or ascites and purified by affinity chromatography.

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. Negative Control (Monoclonal) (Cat. No. 760-2014 / 05266670001)
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.[5] 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. 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.[6,7]
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. The antibody contains 2% of less bovine serum, which is used in the manufacture of the antibody.
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 navifyportal.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 mist or vapours.
	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 760-2511.

Table 2. Recommended staining protocol for Anti-CD43 (L60) antibody with OptiView 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, 64 minutes, 95°C	CC1, 64 minutes, 100°C	ULTRA CC1, 64 minutes, 100°C
Pre-Primary Peroxidase Inhibitor	Selected	Selected	Selected
Antibody (Primary)	4 minutes, 37°C	8 minutes, 37°C	4 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 Anti-CD43 (L60) antibody with *ultra*View 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, Standard	CC1, Standard	ULTRA CC1, Standard
Antibody (Primary)	28 minutes, 37°C	28 minutes, 37°C	24 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.

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]

NEGATIVE REAGENT CONTROL

In addition to staining with Anti-CD43 (L60) 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.

An example of positive control tissues for this antibody is normal tonsil.

STAINING INTERPRETATION / EXPECTED RESULTS

The cellular staining pattern for Anti-CD43 (L60) antibody is membranous and cytoplasmic.

SPECIFIC LIMITATIONS

OptiView detection system is generally more sensitive than *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 sensitivity, specificity, and precision were conducted and the results are listed below.

Sensitivity and Specificity

Table 4. Sensitivity/Specificity of Anti-CD43 (L60) antibody was determined by testing FFPE normal tissues.

Tissue	# positive / total cases	Tissue	# positive / total cases
Cerebrum	1/6	Small intestine	0/5
Cerebellum	3/6	Colon	0/5
Adrenal gland	0/6	Rectum	0/3
Ovary	0/3	Liver	0/5
Pancreas	0/6	Salivary gland	0/4
Lymph node[a]	9/9	Kidney	0/8
Parathyroid gland	0/4	Prostate	0/6
Pituitary gland	0/3	Bladder	0/4
Testis	0/6	Ureter	0/1
Thyroid	0/6	Endometrium	0/6
Breast	0/6	Cervix	0/5
Spleen	9/9	Placenta	0/3
Tonsil	11/11	Skeletal muscle	0/5
Thymus	6/6	Skin	0/5
Bone marrow	4/4	Nerve	0/3
Lung	0/6	Spinal cord	0/1
Heart	0/5	Mesothelium	0/7
Esophagus	0/5	Soft tissue	0/3
Stomach	0/6	Nasopharynx[b]	1/1

[a] Tissues evaluated included normal and reactive lymph node

[b] Chronic inflammation

Table 5. Sensitivity/Specificity of Anti-CD43 (L60) antibody was determined by testing a variety of FFPE neoplastic tissues.

Pathology	# positive / total cases
Glioblastoma (Brain)	0/1
Ependymoma (Brain)	0/1
Meningioma (Brain)	1/1
Oligodendroglioma (Brain)	0/1
Medulloblastoma (Brain)	0/1
Adenoma (Adrenal gland)	0/1
Pheochromocytoma (Adrenal gland)	0/1
Serous carcinoma (Ovary)	0/1
Adult granulosa cell tumor (Ovary)	0/1
Teratoma (Ovary)	0/2
Neuroendocrine carcinoma (Pancreas)	0/1
Ductal adenocarcinoma (Pancreas)	0/1
Seminoma (Testis)	0/1
Embryonal carcinoma (Testis)	0/1
Papillary carcinoma (Thyroid)	0/1
Follicular carcinoma (Thyroid)	0/1
Ductal carcinoma in situ (Breast)	0/1
Invasive ductal carcinoma (Breast)	0/2
Invasive lobular carcinoma (Breast)	0/1
Adenocarcinoma (Lung)	0/1
Squamous cell carcinoma (Lung)	0/1
Small cell carcinoma (Lung)	0/1
Mesothelioma (Pleura)	0/1
Solitary fibrous tumor (Pleura)	0/1
Adenocarcinoma (Esophagus)	0/1
Squamous cell carcinoma (Esophagus)	0/1
Adenocarcinoma (Stomach)	0/1
Gastrointestinal stromal tumor (Stomach)	0/1
Adenocarcinoma (Small intestine)	0/2
Gastrointestinal stromal tumor (Small intestine)	0/1
Adenocarcinoma (Colon)	0/1
Well-differentiated neuroendocrine tumor (Appendix)	0/1
Cholangiocarcinoma (Liver)	0/1
Hepatocellular carcinoma (Liver)	0/1
Pleomorphic adenoma (Salivary gland)	0/1
Warthin tumor (Salivary gland)[a]	0/1
Renal cell carcinoma (Kidney)	0/1
Papillary adenoma (Kidney)	0/1
Adenocarcinoma (Prostate)	0/1
Urothelial carcinoma (Bladder)	0/1
Squamous cell carcinoma (Bladder)	0/1
Diffuse large B-cell lymphoma	85/110
Follicular lymphoma	0/2
MALT lymphoma	1/1
Small lymphocytic lymphoma	6/6
Mantle cell lymphoma	9/9
B-cell lymphoma, NOS	9/12
Plasma cell myeloma (Bone marrow)	1/1
Hodgkin lymphoma	1/7
Extranodal NK/T-cell lymphoma, nasal type	2/2
Peripheral T-cell lymphoma, NOS	43/43
Anaplastic large cell lymphoma	9/9

Pathology	# positive / total cases
Lymphoma, NOS	14/17
Endometrioid adenocarcinoma (Uterus)	0/1
Clear cell carcinoma (Uterus)	0/1
Leiomyoma (Myometrium)	0/1
Adenocarcinoma (Cervix)	0/1
Squamous cell carcinoma (Cervix)	0/1
Angiosarcoma (Skin)	0/1
Basal cell carcinoma (Skin)	0/1
Melanoma (Skin)	0/1
Squamous cell carcinoma (Skin)	0/1
Schwannoma (Spinal cord)	0/2
Liposarcoma (Soft tissue)	0/2
Peripheral nerve sheath tumor (Soft tissue)	0/3
Squamous cell carcinoma (Sinus)	0/1
Adenocarcinoma (Sinus)	0/1
Not specified (Lymph node)	1/1

[a] Evaluation on epithelial tumor cells, the abundant dense lymphocytes in stroma are strongly positive

Precision

Precision studies for Anti-CD43 (L60) 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 the BenchMark GX, BenchMark XT, and BenchMark ULTRA instrument.
- Between platform precision between the BenchMark XT, BenchMark GX, and BenchMark ULTRA 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-run Intermediate Precision. All studies met their acceptance criteria.

CLINICAL PERFORMANCE

Clinical performance data relevant to the intended purpose of Anti-CD43 (L60) 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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7. Directive 2000/54/EC of the European Parliament and Council of 24 June 2020 on the protection of workers from risks related to exposure to biological agents at work.
8. Roche PC, Hsi ED. Immunohistochemistry-Principles and Advances. Manual of Clinical Laboratory Immunology, 6th edition. In: NR Rose, ed. ASM Press; 2002.

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
G	Updates to Warnings and Precautions section. Updated to current template.

INTELLECTUAL PROPERTY

For USA: Rx only

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