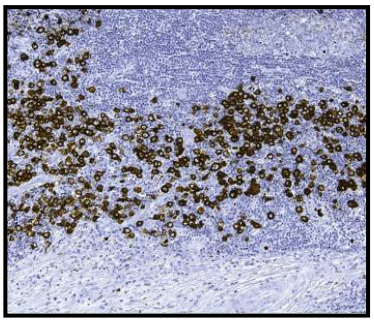
CONFIRM anti-CD15 (MMA) Mouse Monoclonal Primary Antibody

Catalog Number 760-2504



INTENDED USE

This antibody is intended for *in vitro* diagnostic use.

Ventana Medical Systems' CONFIRM anti-CD15 (MMA) Mouse Monoclonal Primary Antibody is a mouse monoclonal antibody (IgM, kappa) directed against a carbohydrate epitope present on most granulocytic cells.[1] This antibody is intended for use to qualitatively identify CD15 by light microscopy in sections of formalin fixed, paraffin embedded tissue stained on the Ventana automated slide stainer. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

SUMMARY AND EXPLANATION

CONFIRM anti-CD15 (MMA) recognizes lacto-N-fucopentose III. Antibodies against CD15 normally react in a strong cell surface membrane staining pattern with granulocytes and granulocyte precursors, monocytes, a subset of tissue macrophages, and activated T-lymphocytes.[1] CONFIRM anti-CD15 (MMA) also reacts against the Reed-Sternberg cells of Hodgkin's disease and, because it recognizes a carbohydrate antigen, is also expressed by a variety of carcinoma types but is negative in malignant mesotheliomas. In addition, CONFIRM anti-CD15 is a pertinent panel marker for thymoma, myxoinflammatory fibroblastic sarcoma, histiocytic lymphoma-sarcoma, peripheral T-cell lymphomas, anaplastic large cell lymphoma, and renal cell carcinoma.[2,3,4,5,6,7]

REAGENT PROVIDED

CONFIRM anti-CD15 (MMA) contains sufficient reagent for staining 50 slides.

One 5 mL dispenser of CONFIRM anti-CD15 (MMA) contains approximately 56 µg of a mouse monoclonal antibody directed against CD15 present in tissue.

The antibody is diluted in 0.05 M Tris-HCl with 2% carrier protein, and 0.10% ProClin 300, a preservative.

Total protein concentration of the reagent is approximately 10 mg/mL. Specific antibody concentration is approximately 11 µg/mL. There is no known irrelevant antibody reactivity observed in this product.

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 Preparation, (4) Quality Control, (5) Troubleshooting, (6) Interpretation of Staining, and (7) General Limitations.

MATERIALS REQUIRED BUT NOT PROVIDED

Staining reagents such as Ventana detection kits (for example, *i*VIEW DAB detection kit or *ultra*View Universal DAB detection kit), and ancillary components, including negative and positive tissue control slides, are not provided.

STORAGE

Store at 2-8ºC. Do not freeze.

To ensure proper reagent delivery and stability of the antibody, after every use the cap must be replaced and the dispenser must be immediately placed 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 automated slide stainer. The recommended tissue fixative is 10% neutral buffered formalin.[8] Heat induced epitope retrieval with an EDTA based basic pH (~8.0) buffer is recommended. Slides should be stained immediately, as antigenicity of cut tissue sections may diminish over time.

It is recommended that positive and negative controls should be run simultaneously with unknown specimens.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. This product contains approximately 2% or less bovine serum which is used in the manufacture of this antibody.
3. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
4. Avoid microbial contamination of reagents.
5. Consult local or state authorities with regard to recommended method of disposal.
6. The preservative in the reagent is ProClin 300. Symptoms of overexposure to ProClin 300 include skin and eye irritation, and irritation of mucous membranes and upper respiratory tract. The concentration of ProClin 300 in this product is less than or equal to 0.10% and does not meet the OSHA criteria for a hazardous substance. Systemic allergic reactions are possible in sensitive individuals.

STAINING PROCEDURE

Ventana primary antibodies have been developed for use on a Ventana automated slide stainer in combination with Ventana detection kits and accessories. A recommended staining protocol for a BenchMark XT/LT instrument with *i*VIEW DAB detection kit (Cat. No. 760-091) and *ultra*View Universal DAB detection kit (Cat. No. 760-500) is listed below 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 package insert for more details regarding immunohistochemistry staining procedures.

Table 1. Recommended Staining Protocol for CONFIRM anti-CD15 (MMA) with *i*VIEW DAB detection kit or *ultra*View Universal DAB detection kit on BenchMark XT/LT Instrument.

Procedure Type	Method
Deparaffinization	Selected
Cell Conditioning (Antigen Unmasking)	Standard Cell Conditioning 1
Enzyme (Protease)	None Required
Antibody (Primary)	Approximately 16 Minutes, 37 °C
Counterstain	Hematoxylin II, 4 Minutes
Post Counterstain	Bluing Reagent, 4 Minutes

Due to variation in tissue fixation and processing, it may be necessary to increase or decrease the primary antibody incubation, cell conditioning or protease pretreatment based on individual specimens and detection used. For further information on fixation variables, refer to "Immunohistochemistry Principles and Advances".[9]

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POSITIVE TISSUE CONTROL

Examples of positive control tissues for CONFIRM anti-CD15 (MMA) are Hodgkin's lymphoma. Reed-Sternberg cell membranes should stain positively.

STAINING INTERPRETATION

The cellular staining pattern for CONFIRM anti-CD15 (MMA) is membranous.

SPECIFIC LIMITATIONS

This antibody has been optimized for a 16 minute incubation time on BenchMark XT/LT automated slide stainers in combination with Ventana detection kits, however the user must validate results obtained with this reagent or any other detection kit used that is not listed above. CD15 specificity shows staining in normal cells expressed in myoepithelial cells in prostate, glandular epithelial cells, and myelomonocytic cells.

Examples of normal cells exhibiting occasional cross-reactivity with clone MMA include oesophageal squamous mucosa and myoepithelial staining in prostate.

PERFORMANCE CHARACTERISTICS

1. Immunoreactivity of CONFIRM anti-CD15 (MMA) was determined by testing formalin fixed, paraffin embedded normal and neoplastic tissues. For normal tissues, the following stained negatively with CONFIRM anti-CD15 (MMA) except for expected positive staining of neutrophils, granulocytes, parenchyma, and glandular cells when present. For normal tissues, results are as follows: brain cerebellum (0/3), adrenal gland (0/3), ovary (0/3), pancreas (0/3), parathyroid (0/3), testis (0/3), thyroid (0/3), breast (1/3), spleen (0/3), tonsil (2/3), thymus (0/3), bone marrow (0/3), lung (0/3), heart (0/3), esophagus (3/3), stomach (2/3), intestine (3/3), colon (0/3), liver (0/3), salivary gland (0/3), kidney (3/3), prostate (3/3), uterus (3/3), cervix (0/3), striated muscle (0/3), skin (0/3), nerve (0/3), hypophysis (0/3), mesothelium (0/3). For neoplastic tissues, results are as follows: atypical meningioma (0/1), glioblastoma (0/1), ependymoma (0/1), oligodendroglioma (0/1), ovarian serous papillary adenocarcinoma (0/1), ovarian mucous papillary adenocarcinoma (0/1), islet cell carcinoma (0/1), pancreatic adenocarcinoma (0/1), testicular seminoma and embryonal carcinoma (0/2), medullary thyroid carcinoma (1/1), papillary thyroid carcinoma (1/1), lobular and infiltrating breast carcinoma (2/2), diffuse B-cell lymphoma in spleen (0/1), small cell lung carcinoma (0/1), squamous cell lung carcinoma (1/1), lung adenocarcinoma (1/1), esophageal squamous cell carcinoma (1/1), mucinous adenocarcinoma in stomach (0/1), intestinal adenocarcinoma (1/1), colorectal and intestinal mesenchymoma (0/3), colorectal adenocarcinoma (1/1), hepatocellular carcinoma (0/1), hepatoblastoma (0/1), clear cell carcinoma (1/1), adenocarcinoma in prostate (1/1), transitional cell carcinoma in prostate and bladder (2/2), uterine leiomyoma (0/1), endometrial carcinoma (0/1), cervical squamous cell carcinoma (1/1), embryonal rhabdomyosarcoma (0/1), rectal melanoma (0/1), neurofibroma and neuroblastoma (0/2), mesothelioma (0/1), Hodgkin's lymphoma (1/1), diffuse type lymphoma (0/1),diffuse type non-Hodgkin's lymphoma (0/1), leiomyosarcoma in smooth muscle and bladder (0/2), osteosarcoma (0/1), and spindle cell rhabdomyosarcoma (0/1).
2. Intra-run reproducibility was determined by staining duplicate slides containing the same tissues from duplicate samples types across the dynamic range on a BenchMark XT instrument. 28 of 28 Hodgkin cases tested scored equivalently and 25 of 25 normal tissues tested scored equivalently.

REFERENCES

1. Pinkus GS., P. Thomas, and J.W. Said. Leu-M1--A Marker for Reed-Sternberg Cells in Hodgkin's Disease: An Immunoperoxidase Study of Paraffin-Embedded Tissues. Am. J. Pathol. 1985; Vol. 119, p. 244-252.
2. Pan CC, Chen PC, Chou TY, Chiang H., Expression of calretinin and other mesothelioma-related markers in thymic carcinoma and thymoma. Hum. Pathol. 2003 Nov 34 (11):1155-62.
3. Montgomery EA, Devaney KO, Giordano TJ, Weiss , Inflammatory myxohyaline tumor of distal extremities with virocyte or Reed-Sternberg-like cells: a distinctive lesion with features simulating inflammatory conditions, Hodgkin's disease, and various sarcomas. Mod. Pathol. 1998 Apr 11(4):384-91.
4. Cao M, Eshoa C, Schultz, Black J, Zu Y, Chang CC. Primary central nervous system histiocytic sarcoma with relapse to mediastinum: a case report and review of the literature. Arch. Pathol. Lab. Med. 2007 Feb 131 (2): 301-5.
5. Barry TS, Jaffe ES, Sorbara L, Raffeld M, Pittaluga S. Peripheral T-cell lymphomas expressing CD30 and CD15. Am.J.Surg. Pathol. 2003 Dec 27 (12):1513-22.
6. Vassallo J, Lamant L, Brugieres L, Gaillard F, Campo E, Brousset P, Delsol G. ALK-Positive Anaplastic Large Cell Lymphoma Mimicking Nodular Sclerosis Hodgkin's Lymphoma: Report of 10 Cases. Am. J. Surg. Pathol. 2006 Feb 30 (2): 223-229.
7. Ordóñez NG. The diagnostic utility of immunohistochemistry in distinguishing between mesothelioma and renal cell carcinoma: a comparative study. Mesothelioma. Hum. Pathol. 2004 Jun 35(6):697-710.
8. Sheehan DC, Hrapchak BB. Theory and Practice of Histotechnology, 2nd Edition. The C.V. Mosby Company, St. Louis, 1980.
9. Roche PC, Hsi ED. Immunohistochemistry-Principles and Advances. Manual of Clinical Laboratory Immunology, 6th edition. (NR Rose Ed.) ASM Press, 2002.

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