CONFIRM anti-CD56 (123C3) Mouse Monoclonal Primary Antibody

REF 790-4465

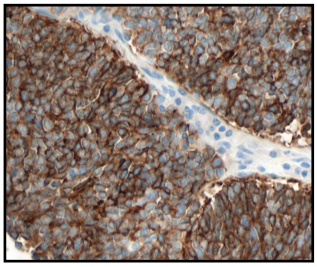

Figure 1. Small Cell Lung Carcinoma Stained with CONFIRM anti-CD56 (123C3) Mouse Monoclonal Antibody and the *ultra*View Universal DAB Detection Kit

INTENDED USE

Ventana Medical Systems' (Ventana) CONFIRM anti-CD56 (123C3) Mouse Monoclonal Primary Antibody (CONFIRM anti-CD56 (123C3)) is directed against the CD56 molecule or neural cell adhesion molecule expressed by most neuroectodermally derived cell lines, tissues and neoplasms. It is also expressed on some mesodermally derived tumors, on natural killer cells, and NK cell lymphomas. This antibody exhibits a membrane/cytoplasmic staining pattern and may be used to aid in the identification of small cell carcinomas, neuroblastoma, and rhabdomyosarcoma. 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

CONFIRM anti-CD56 (123C3) is a mouse monoclonal antibody produced against the CD56 molecule. CD56 is identical to the neural cell adhesion molecule (N-CAM), a membrane glycoprotein containing immunoglobulin-like domains, which is involved in the interaction of cells in the peripheral and central nervous systems.[1,2] The CD56 protein is highly expressed in both developing and adult human brain and plays an essential role in neurogenesis, neuronal migration, neurite growth, and formation of nerve fibers and synapses.[3,4] Normal tissues expressing CD56 include natural killer cells, neuroendocrine glands, neural tissue and cardiomyocytes.[3] CD56 is also expressed in the majority of neuroblastoma, rhabdomyosarcoma, small cell lung cancer, brain tumors, multiple myelomas and acute myeloid leukemia.[5]

REAGENT PROVIDED

CONFIRM anti-CD56 (123C3) contains sufficient reagent for staining 50 tests.

One 5 mL dispenser of CONFIRM anti-CD56 (123C3) contains approximately 40 µg of a mouse monoclonal antibody produced as supernatant.

The antibody is diluted in Phosphate buffer with carrier protein and 0.05% ProClin 300, a preservative.

Total protein concentration of the reagent is approximately 19 mg/mL. Specific antibody concentration is approximately 8 µg/mL. There is no known non-specific antibody reactivity observed in this product.

Refer to the appropriate Ventana detection kit package insert for detailed descriptions of: (1) Principles and Procedures, (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 (*ultra*View Universal DAB Detection Kit), and ancillary components, including negative and positive tissue controls, 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 automated slide stainer. The recommended tissue fixative is 10% neutral buffered formalin.[6] 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 use.
2. This product contains 1% or less bovine serum which is used in the manufacture of the 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 and/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 the BenchMark XT/BenchMark ULTRA instruments with *ultra*View Universal DAB Detection Kit (REF 760-500) 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 CONFIRM anti-CD56 (123C3) with *ultra*View Universal DAB Detection Kit on a BenchMark XT/BenchMark ULTRA instrument.

Procedure Type	Method
Deparaffinization	Selected
Cell Conditioning (Antigen Unmasking)	Standard Cell Conditioning 1
Enzyme (Protease)	None required
Antibody (Primary)	BenchMark XT instrument Approximately 16 Minutes, 37°C BenchMark ULTRA instrument Approximately 28 Minutes, 36°C
Counterstain	Hematoxylin II, 4 Minutes
Post Counterstain	Bluing Reagent, 4 Minutes

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".[7]

POSITIVE TISSUE CONTROL

Examples of positive control tissues for this antibody are normal pancreas and brain.

STAINING INTERPRETATION

The cellular staining pattern for CONFIRM anti-CD56 (123C3) is membrane/cytoplasmic.

SPECIFIC LIMITATIONS

This antibody has been optimized for a 16 minute incubation time on a BenchMark XT instrument and 28 minutes on a BenchMark ULTRA instrument in combination with *ultra*View Universal DAB Detection Kit but the user must validate results obtained with this reagent.

PERFORMANCE CHARACTERISTICS

1. Specificity of CONFIRM anti-CD56 (123C3) was determined by testing formalin fixed, paraffin embedded normal and neoplastic tissues.

   For normal tissues, results are as follows: (3/3) cerebrum, (3/3) cerebellum, (3/3) adrenal gland, (1/3) ovary, (1/4) pancreas, (0/3) parathyroid, (3/3) hypophysis, (2/3) testis, (0/3) thyroid gland, (0/3) breast, (0/5) spleen, (0/3) tonsil, (0/3) thymus, (0/3) myeloid, (0/8) lung, (3/4) heart, (0/3) esophagus, (2/3) stomach, (0/3) small intestine, (0/3) colon, (0/3) liver, (0/3) salivary gland, (0/5) kidney, (0/3) prostate, (0/3) endometrium, (0/3) cervix, (0/4) skeletal muscle, (0/3) skin, (5/5) normal nerve, (0/3) mesothelium and lung.

   For neoplastic tissues, results are as follows: (1/1) glioblastoma, (0/1) atypical meningioma, (1/1) malignant ependymoma, (1/1) oligodendroglioma, (1/1) serous papillary adenocarcinoma, (0/1) mucinous papillary adenocarcinoma, (0/1) islet cell carcinoma, (2/2) pancreatic carcinoma, (0/1) seminoma, (0/1) embryonal carcinoma, (1/1) medullary carcinoma, (0/1) papillary carcinoma, (0/1) intraductal carcinoma, (0/1) lobular breast carcinoma in situ, (0/1) invasive ductal carcinoma, (0/1) diffuse B-cell lymphoma, (33/35) small cell undifferentiated carcinoma, (0/1) lung squamous cell carcinoma, (0/1) lung adenocarcinoma, (0/1) esophagus squamous cell carcinoma, (0/1) esophagus adenocarcinoma, (0/1) stomach mucinous adenocarcinoma, (0/1) small intestine adenocarcinoma, (0/3) GIST, (0/1) colon adenocarcinoma, (0/1) rectal adenocarcinoma, (0/1) hepatocellular carcinoma, (0/1) hepatoblastoma, (0/2) clear cell carcinoma, (0/1) prostate adenocarcinoma, (0/1) transitional cell prostate carcinoma, (0/1) leiomyoma, (0/1) endometrial adenocarcinoma, (15/19) rhabdomyosarcoma, (0/1) malignant melanoma, (0/1) basal cell carcinoma, (0/3) squamous cell carcinoma, (0/1) neurofibroma, (11/11) neuroblastoma, (0/1) epithelial malignant mesothelioma, (0/3) diffuse malignant lymphoma, (0/1) Hodgkin's lymphoma, (0/1) transitional cell carcinoma with squamous metaplasia, (5/20) leiomyosarcoma, (1/1) osteosarcoma, (7/7) retinoblastoma, (10/11) nephroblastoma, (0/2) acute lymphocytic leukemia, (0/2) chronic lymphocytic leukemia and (0/1) acute granulocytic leukemia.
2. Inter-lot reproducibility was determined by testing 3 lots across 1 multi-tissue block (3 tissues per block, 2 slides per lot) on a BenchMark XT instrument. 18 out of 18 tested across all 3 lots scored equivalently.
3. Inter-run repeatability was determined by staining 2 multi-tissue blocks (3 tissues per block for a total of 6 tissues) across 5 slides on a BenchMark XT instrument over a 5 day non-consecutive period. 150 out of 150 samples tested scored equivalently.
4. Intra-run reproducibility was determined by staining 2 multi-tissue blocks (3 tissues per block) across 14 slides on a BenchMark XT instrument. 84 out of 84 samples tested scored equivalently.
5. Intra-platform reproducibility was determined by staining 2 multi-tissue blocks (3 tissues per block) across 5 slides on 3 BenchMark XT instruments. 90 out of 90 samples tested scored equivalently.
6. Intra-platform reproducibility was determined by staining 1 multi-tissue block (3 tissues per block) across 5 slides on 3 BenchMark ULTRA instruments. 45 out of 45 samples tested scored equivalently.
7. Inter-platform reproducibility was determined by staining 1 multi-tissue block (3 tissues per block) across 5 slides on 3 BenchMark XT instruments and 3 BenchMark ULTRA instruments. 90 out of 90 samples tested scored equivalently.
8. Compatible with BenchMark XT and BenchMark ULTRA instruments and *i*VIEW DAB and *ultra*View Universal DAB Detection Kits.

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