

MOC-31

Concentrated and Prediluted Monoclonal Antibody
901-403-060223

BIOCARE
M E D I C A L

Available Product Formats				
Format	Catalog Number	Description	Dilution	Diluent
Concentrate	CM 403 A, C	0.1, 1.0 mL	1:200	Renoir Red
Predilute	PM 403 AA	6.0 mL	Ready-to-use	N/A
ONCORE Pro	OPAI 403 T60	60 tests	Ready-to-use	N/A
UltraLine – For BenchMark	AVI 403 G	6.0 mL	Ready-to-use	N/A

Intended Use:

For In Vitro Diagnostic Use

MOC-31 is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of Ep-CAM glycoprotein by immunohistochemistry (IHC) in formalin-fixed paraffin-embedded (FFPE) human tissues. The clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

Summary and Explanation:

MOC-31, also known as Epithelial Specific Antigen/Ep-CAM, consists of two 34 and 39 kDa glycoproteins. These glycoproteins are located on the cell membrane surface and in the cytoplasm of virtually all epithelial cells with the exception of most squamous epithelia, hepatocytes, renal proximal tubular cells, gastric parietal cells and myoepithelial cells. MOC-31 is used in a panel of antibodies as a negative marker for mesothelioma; and a negative stain for MOC-31 has been shown to exclude lung adenocarcinoma. MOC-31 is useful in differentiating tumors of unknown origin in liver cancers and distinguishing cholangiocarcinoma (+) from hepatocellular carcinomas (-). MOC-31 may be advantageous in the demonstration of epithelial cell differentiation in cases where anti-cytokeratins are not clearly positive or in cases where a false positivity for cytokeratin cannot be excluded, such as in submesothelial cells.

Principle of Procedure:

Antigen detection in tissues and cells is a multi-step immunohistochemical process. The initial step binds the primary antibody to its specific epitope. After labeling the antigen with a primary antibody, a one-, two- or three-step detection procedure can be employed. The one-step procedure will feature an enzyme-labeled polymer that binds to the primary antibody. A two-step procedure will feature a secondary antibody added to bind to the primary antibody. An enzyme-labeled polymer is then added to bind to the secondary antibody. The three-step detection procedure will feature a secondary antibody added to bind to the primary antibody followed by a linker antibody step for maximum binding. An enzyme-labeled polymer is then added to bind to the linker antibody. These detections of the bound antibodies are evidenced by a colorimetric reaction.

Source: Mouse monoclonal

Species Reactivity: Human, others not tested

Clone: MOC-31

Isotype: IgG1

Protein Concentration: Call for lot specific Ig concentration.

Epitope/Antigen: Ep-CAM

Cellular Localization: Cell membrane

Positive Tissue Control: Colon and breast cancers

Known Applications: Immunohistochemistry (formalin-fixed paraffin-embedded tissues)

Supplied As: Buffer with protein carrier and preservative

Storage and Stability:

Store at 2°C to 8°C. The product is stable to the expiration date printed on the label, when stored under these conditions. Do not use after expiration date. Diluted reagents should be used promptly; any remaining reagent should be stored at 2°C to 8°C.

Protocol Recommendations (intelliPATH FLX® and manual use):

Peroxide Block: Block for 5 minutes with Peroxidized 1.

Digestion Method: Digest with Pepsin enzyme for 20 minutes at RT or for 5 minutes at 37°C.

Protein Block (Optional): Incubate for 5-10 minutes at RT with Background Punisher.

Primary Antibody: Incubate for 30-45 minutes at RT.

Probe: Incubate for 10 minutes at RT with a secondary probe.

Polymer: Incubate for 10-20 minutes at RT with a tertiary polymer.

Chromogen: Incubate for 5 minutes at RT with Biocare's DAB - OR - Incubate for 5-7 minutes at RT with Warp Red.

Counterstain: Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.

Technical Note:

This antibody, for intelliPATH FLX and manual use, has been standardized with MACH 4 detection system. Use TBS for washing steps.

Protocol Recommendations (ONCORE™ Pro Automated Slide Staining System):

OPAI403 is intended for use with the ONCORE Pro. Refer to the User Manual for specific instructions for use. Protocol parameters in the Protocol Editor should be programmed as follows:

Protocol Name: MOC-31

Protocol Template (Description): Ms HRP Template 1

Dewaxing (DS Buffer Option): DSE-50

Antigen Retrieval (AR Option): AR2, low pH; 40°C

Block Option: Buffer

Reagent Name, Time, Temp.: MOC-31, 59 min., 25°C

Protocol Recommendations (Ventana BenchMark ULTRA):

AVI403 is intended for use with the BenchMark ULTRA. Refer to the User Manual for specific instructions for use. Recommended protocol parameters are as follows:

Template/Detection: OptiView DAB IHC

Pretreatment Protocol: CC1 32 minutes

Peroxidase: Pre Primary Peroxidase Inhibitor

Primary Antibody: 32 minutes, 36°C

Limitations:

The optimum antibody dilution and protocols for a specific application can vary. These include, but are not limited to fixation, heat-retrieval method, incubation times, tissue section thickness and detection kit used. Due to the superior sensitivity of these unique reagents, the recommended incubation times and titers listed are not applicable to

MOC-31

Concentrated and Prediluted Monoclonal Antibody
901-403-060223

BIOCARE
M E D I C A L

Limitations Cont'd:

other detection systems, as results may vary. The data sheet recommendations and protocols are based on exclusive use of Biocare products. Ultimately, it is the responsibility of the investigator to determine optimal conditions.

Quality Control:

Refer to CLSI Quality Standards for Design and Implementation of Immunohistochemistry Assays; Approved Guideline-Second edition (I/LA28-A2) CLSI Wayne, PA USA (www.clsi.org). 2011

Precautions:

1. This antibody contains less than 0.1% sodium azide. Concentrations less than 0.1% are not reportable hazardous materials according to U.S. 29 CFR 1910.1200, OSHA Hazard communication and EC Directive 91/155/EC. Sodium azide (NaN₃) used as a preservative is toxic if ingested. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. Upon disposal, flush with large volumes of water to prevent azide build-up in plumbing. (Center for Disease Control, 1976, National Institute of Occupational Safety and Health, 1976) (5)
2. Specimens, before and after fixation, and all materials exposed to them should be handled as if capable of transmitting infection and disposed of with proper precautions. Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents and specimens. If reagents or specimens come into contact with sensitive areas, wash with copious amounts of water. (6)
3. Microbial contamination of reagents may result in an increase in nonspecific staining.
4. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change.
5. Do not use reagent after the expiration date printed on the vial.
6. The SDS is available upon request and is located at <http://biocare.net>.

Troubleshooting:

Follow the antibody specific protocol recommendations according to data sheet provided. If atypical results occur, contact Biocare's Technical Support at 1-800-542-2002.

References:

1. Morrison C, Marsh W Jr, Frankel WL. A comparison of CD10 to pCEA, MOC-31, and hepatocyte for the distinction of malignant tumors in the liver. *Mod Pathol.* 2002 Dec;15(12):1279-87.
2. Proca DM, *et al.* MOC31 immunoreactivity in primary and metastatic carcinoma of the liver. Report of findings and review of other utilized markers. *Appl Immunohistochem Mol Morphol.* 2000 Jun;8(2):120-5.
3. Pai RK, West RB. MOC-31 exhibits superior reactivity compared with Ber-EP4 in invasive lobular and ductal carcinoma of the breast: a tissue microarray study. *Appl Immunohistochem Mol Morphol.* 2009 May; 17(3):202-6.
4. Nelson G, Ordonez, MD. Value of the MOC-31 monoclonal antibody in differentiating epithelial pleural mesothelioma from lung adenocarcinoma. *Human Pathol.* 1998 Feb; 29(2):166-9.
5. Center for Disease Control Manual. Guide: Safety Management, NO. CDC-22, Atlanta, GA. April 30, 1976 "Decontamination of Laboratory Sink Drains to Remove Azide Salts."
6. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Fourth Edition CLSI document M29-A4 Wayne, PA 2014.

VP Echelon Series antibodies are developed solely by Biocare Medical LLC and do not imply approval or endorsement of Biocare's antibodies by Ventana Medical Systems, Inc. Biocare and Ventana are not affiliated, associated or related in any way. Ventana®, BenchMark®, *ultraView* and OptiView are trademarks of Roche.