



CA 125

Concentrated and Prediluted Monoclonal Antibody

Control Number: 901-101-111408

ISO
9001:2000
CERTIFIED

Catalog Number: CM 101 AK, BK, CK PM 101 AA
Description: 0.1, 0.5, 1.0 ml, concentrated 6.0 ml, prediluted
Dilution: 1:200-1:400 Ready-to-use
Diluent: Renoir Red N/A

Probe: N/A

Polymer: Incubate for 30 minutes at RT with a Polymer.

Chromogen:

Incubate for 5 minutes at RT when using BIOCARE's DAB. - OR - Incubate for 10 minutes at RT when using BIOCARE's Vulcan Fast Red.

Intended Use:

For In Vitro Diagnostic Use

Summary and Explanation:

CA125 recognizes an epitope on a molecule called Cancer Antigen 125 (CA125). Studies have show that CA125 reacts with approximately 80% of epithelial ovarian neoplasms of serous, endometrioid, clear cell and undifferentiated types. No reactivity has been shown for mucinous ovarian tumors or in germ cell or hematopoietic tumors. CA125 reacts with both normal tissues and neoplasms of fallopian tube, endometrium, endocervix and mesothelioma. It does not react with colon cancer. Normal tissues such as breast, liver, skin, kidney and spleen are negative.

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 MACH 2 enzyme labeled polymer is added to bind to the primary antibody. The detection of the bound antibody is evidenced by a colorimetric reaction.

Source: Mouse monoclonal

Species Reactivity: Human; others not tested

Clone: OC125

Isotype: IgG1

Total Protein Concentration: ~10 mg/ml. Call for lot specific Ig Concentration.

Epitope/Antigen: Cancer Antigen 125

Cellular Localization: Cytoplasmic

Positive Control: Ovarian cancer or endocervix

Normal Tissue: N/A

Abnormal Tissue: Ovarian or breast cancer

Known Applications:

Immunohistochemistry (formalin-fixed paraffin-embedded tissues)

Supplied As: Buffer with protein carrier and preservative.

Renoir Red (PD904)

Storage and Stability:

Store at 2°C to 8°C. Do not use after expiration date printed on vial. If reagents are stored under conditions other than those specified in the package insert, they must be verified by the user. Diluted reagents should be used promptly; any remaining reagent should be stored at 2°C to 8°C.

Protocol Recommendations

Peroxide Block:

If using an HRP system, block for 5 minutes with BIOCARE's PEROXIDAZED 1.

Pretreatment Solution (recommended): Diva

Pretreatment Protocol:

Heat Retrieval Method:

Retrieve sections under pressure usings BIOCARE'S Decloaking Chamber, followed by a wash in distilled water. Alternatively, steam tissue sections for 45-60 minutes. Allow solution to cool for 20 minutes then wash in distilled water.

Protein Block:

Incubate for 10-15 minutes at RT with BIOCARE's Background Sniper.

Primary Antibody: Incubate for 30 minutes at RT.

Technical Note:

This antibody has been standardized with BIOCARE's MACH 2 detection system. It can also be used on an automated staining system and with other BIOCARE polymer detection kits. Use TBS buffer for washing steps.

Performance Characteristics:

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 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. These products are tools that can be used for interpretation of morphological findings in conjunction with other diagnostic tests and pertinent clinical data by a qualified pathologist.

Quality Control:

Refer to NCCLS Quality Assurance for Immunocytochemistry approved guidelines, December 1999 MM4-A Vol.19 No.26 for more information about Tissue Controls.

Precautions:

Reagents contain less than 0.1% Sodium azide. Concentration less than 0.1% is not reportable hazardous material according to U.S. 29 CFR 1910.1200, ODHA 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)

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 in contact with sensitive areas, wash with copious amounts of water.

Minimize microbial contamination of reagents or increase in nonspecific staining may occur. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change.

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.

Limitations and Warranty:

There are no warranties, expressed or implied, which extend beyond this description. BIOCARE is not liable for property damage, personal injury, or economic loss caused by this product.

References:

1. Athanassiadou P et al. Expression of cathepsin-D, CA125 and epidermal growth factor receptor in imprint smears of ovarian carcinoma. Gynecol Obstet Invest 1997; 43(2):125-30.
2. Rabinerson D, Kaplan B, Levavi H, Neri A. The biology of ovarian cancer of epithelial origin. CA125. Isr J Med Sci 1996 Nov;32(11):1128-33.
3. Brown RW et al. Immunohistochemical identification of tumor markers in metastatic adenocarcinoma. A diagnostic adjunct in the determination of primary site. Am J Clin Pathol 1997. Jan;107(1):12-9.



**CA 125**

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References cont'd:

4. Podczaski E, Kaminski P et al. Tissue CA 125 and CA 19-9 in malignant, mixed mesodermal tumors of the uterus. *Gynecol Oncol* 1993 Apr;49(1):56-60.
5. Bischof P. What do we know about the origin of CA 125? *Eur J Obstet Gynecol Reprod Biol* 1993 Apr;49 (1-2):93-8.
6. Kabawat SE et al. Tissue distribution of a coelomic-epithelium-related antigen recognized by the monoclonal antibody OC125. *Int J Gynecol Pathol* 1983;2(3):275-85.
7. 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."
8. National Committee for Clinical Laboratory Standards(NCCLS). Protection of laboratory workers from infectious diseases transmitted by blood and tissue; proposed guideline. Villanova, PA 1991;7(9). Order code M29-P.



CA 125

Prediluted Mouse Monoclonal Antibody

Control Number: 901-101IP-111708

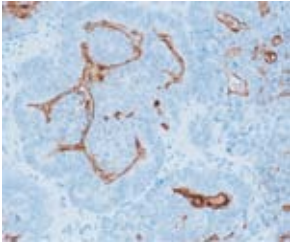
Catalog Number: IP 101 G10
Description: 10 ml, predilute

Intended Use:

For In Vitro Diagnostic Use

Summary and Explanation:

CA125 recognizes an epitope on a molecule called Cancer Antigen 125 (CA125). Studies have shown that CA125 reacts with approximately 80% of epithelial ovarian neoplasms of serous, endometrioid, clear cell and undifferentiated types. No reactivity has been shown for mucinous ovarian tumors or in germ cell or hematopoietic tumors. CA125 reacts with both normal tissues and neoplasms of fallopian tube, endometrium, endocervix and mesothelioma. It does not react with colon cancer. Normal tissues such as breast, liver, skin, kidney and spleen are negative.



Ovarian cancer stained with CA 125 antibody.

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, an affinity-purified, secondary antibody is added to bind to the primary antibody. An enzyme label is then added to bind to the secondary antibody; this detection of the bound antibody is evidenced by a colorimetric reaction.

Source: Mouse monoclonal**Species Reactivity:** Human; others not tested**Clone:** OC125**Isotype:** IgG1**Antibody Category:** Carcinoma, ovarian cancer**Epitope/Antigen:** Cancer Antigen 125**Total Protein Concentration:** Call for lot specific Ig Concentration.**Cellular Localization:** Cytoplasmic**Positive Control:** Ovarian cancer or endocervix**Normal Tissue:** N/A**Abnormal Tissue:** Ovarian cancer**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. Do not use after expiration date printed on vial. If reagents are stored under conditions other than those specified in the package insert, they must be verified by the user. Diluted reagents should be used promptly; any remaining reagent should be stored at 2°C to 8°C.

Protocol Recommendations**Pretreatment Solution (recommended):** Diva**Pretreatment Protocol:****Heat Retrieval Method:**

Retrieve sections under pressure using BIOCARE's Decloaking Chamber, followed by a wash in distilled water. Alternatively, steam tissue sections for 45-60 minutes. Allow solution to cool for 20 minutes then wash in distilled water.

Peroxide Block:

Block for 5 minutes at RT.

Primary Antibody: Incubate for 30 minutes at RT.**Secondary:** Incubate for 10 minutes at RT.**Tertiary:** Incubate for 10 minutes at RT.**Chromogen:**

Incubate for 5 minutes with DAB at RT.

Counterstain:

1. Rinse with deionized water. 2. Incubate for 5 minutes with automated Hematoxylin. 3. Rinse with TBS Buffer for 1 minute followed by a rinse with deionized water.

Quality Statement:

BIOCARE protocols have been standardized using in-house antibodies, detection and accessory reagents for use on the *intelliPATH* FLX automated stainer. Recommended staining protocols are specified in the datasheet of the antibody of interest. Pre-optimized *intelliPATH* FLX protocols with preset parameters can be displayed, printed and edited according to the procedure in the operator's manual. Refer to the operator's manual for additional instruction to navigate *intelliPATH* FLX software and stainer. Use TBS for washing steps unless otherwise specified.

Performance Characteristics:

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 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. These products are tools that can be used for interpretation of morphological findings in conjunction with other diagnostic tests and pertinent clinical data by a qualified pathologist.

Quality Control:

Refer to NCCLS Quality Assurance for Immunocytochemistry approved guidelines, December 1999 MM4-A Vol.19 No.26 for more information about Tissue Controls.

Precautions:

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)

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 in contact with sensitive areas, wash with copious amounts of water.

Microbial contamination of reagents may result in an increase in nonspecific staining. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change. The MSDS is available upon request.

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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.

Limitations and Warranty:

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References:

1. Athanassiadou P et al. Expression of cathepsin-D, CA125 and epidermal growth factor receptor in imprint smears of ovarian carcinoma. Gynecol Obstet Invest 1997; 43(2):125-30.
2. 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."
3. National Committee for Clinical Laboratory Standards(NCCLS). Protection of laboratory workers from infectious diseases transmitted by blood and tissue; proposed guideline. Villanova, PA 1991;7(9). Order code M29-P.

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