Product Datasheet and Instructions for Use

Product Code:
MP-101-CMK01 (0.1ml conc)
MP-101-CMK05 (0.5ml conc)
MP-101-CMK1 (1ml conc)
MP-101-PM6 (6ml RTU)

Product Description:
CA 125
Concentrated and Prediluted Monoclonal Antibody
Control Number: 901-101-111408
ISO 9001:2000 CERTIFIED

Summary and Explanation:
Antigen detection, in tissues and cells, is a multi-step immunohistochemical process. The initial step binds the primary antibody to its specific epitope. After labelling the antigen with a primary antibody, a universal, 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.
CA125 recognises 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 tumours 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.

Intended Use: For In Vitro Diagnostic Use

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.
   Sensitivity Enhancing Antibody Diluent C (MP-904)

**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.
Instructions for Use:

Endogenous Peroxidase Block
Block all endogenous peroxidase activity by incubating the sections for 5 minutes with the MenaPath Peroxide Block. Rinse slides in water, and then rinse well in buffer.

Pretreatment Protocol:
Retrieve sections with MenaPath Access Supreme Solution using the MenaPath Access Retrieval Unit 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 sections for 10-15 minutes at room temperature with the MenaPath Background Blocker with Casein

Primary Antibody
Dilute antibody 1:200-1:400 with MenaPath Sensitivity Enhancing Antibody Diluent C (MP-904). Incubate sections for 30 minutes at room temperature. Rinse slides x3 with buffer. Do not dilute MP-101-PM6 as it is ready to use.

Universal Probe
Incubate sections for 10-20 minutes at room temperature with the MenaPath X-Cell Plus Universal Probe. Rinse slides x3 with buffer

HRP Polymer
Incubate sections for 10-25 minutes at room temperature with the MenaPath X-Cell Plus HRP Polymer. Rinse slides x3 in buffer.

Chromogen
Incubate sections for 5 minutes at room temperature with MenaPath X-Cell Plus Liquid Stable DAB. Rinse x3 with buffer.

Counterstain:
Incubate for 30-60 seconds with MenaPath Haematoxylin. Rinse with deionized water. Apply Bluing solution for 1 minute. Dehydrate, Clear and Mount
Technical Note: Use TBS buffer for wash 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 MenaPath 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.

Troubleshooting: Follow the antibody specific protocol recommendations according to data sheet provided. If atypical results occur, contact Menarini’s Technical Service Helpline: on 01189 444130.
Limitations and Warranty
There are no warranties, expressed or implied, which extend beyond this description. Menarini is not liable for damages of any kind including: personal injury, or economic loss caused by this product.

Reference: