Cytokeratin 7 (CK7)  
Concentrated and Prediluted Monoclonal Antibody  
901-061-121417

<table>
<thead>
<tr>
<th>Catalog Number:</th>
<th>Description:</th>
<th>Diluent:</th>
<th>Protocol Recommendations (intelliPATH and manual use)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CM 061 A, B, C</td>
<td>0.1, 0.5, 1.0 ml, concentrated</td>
<td>Da Vinci Green</td>
<td>Cont’d:</td>
</tr>
<tr>
<td>PM 061 AA</td>
<td>6.0 ml, prediluted</td>
<td>N/A</td>
<td>Digestion Method:</td>
</tr>
<tr>
<td>IPI 061 G10</td>
<td>10 ml, prediluted</td>
<td>N/A</td>
<td>Digest with Pepsin enzyme for 5 minutes at 37°C –or- for 15 minutes at RT.</td>
</tr>
<tr>
<td>OAI 061 T60</td>
<td>60 tests, prediluted</td>
<td>N/A</td>
<td>Protein Block (Optional): Incubate for 5-10 minutes at RT with Biocare's Background Punisher.</td>
</tr>
</tbody>
</table>

**Intended Use:**  
For In Vitro Diagnostic Use  
Cytokeratin 7 (CK7) [OV-TL 12/30] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of cytokeratin 7 (CK7) protein 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:**  
Cytokeratin 7 is an intermediate filament protein (IFP) of 54 kDa that recognizes the simple epithelium found in most glandular and transitional epithelia; but not that which is found in stratified squamous epithelia. This monoclonal antibody [OV-TL 12/30] is highly specific to cytokeratin 7 and shows no cross reaction with other IFPs. Cytokeratin 7 is a basic cytokeratin, and is expressed in epithelial cells of ovary, lung, and breast, but not of colon or gastrointestinal tract. It is often used in conjunction with cytokeratin 20 in distinguishing ovarian, pulmonary, and breast carcinomas (CK7+) from colon carcinomas (CK7-).

**Protocol Recommendations:**  
**ONCORE Automated Slide Staining System:**  
OAI061 is intended for use with the ONCORE Automated Slide Staining System. Refer to the User Manual for specific instructions for use.  
**Diluent:**  
Da Vinci Green  
**Reagent:**  
N/A  
**Dilution:**  
1:100  
**Ready-to-use**  
**Cellular Localization:**  
Cytoplasmic  
**Source:**  
Mouse monoclonal  
**Technical Note:**  
This antibody, for intelliPATH and manual use, has been standardized with Biocare's MACH 4 detection system. Use TBS for washing steps.  
**Limitations:**  
The optimum antibody dilution and protocols for a specific application can vary. These include, but are not limited to fixed, 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 titer levels 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. The clinical interpretation of any positive or negative staining should be evaluated within the context of clinical presentation, morphology and other histopathological criteria by a qualified pathologist. The clinical interpretation of any positive or negative staining should be complemented by morphological studies using proper positive and negative internal and external controls as well as other diagnostic tests.

**Intestinal Permeability**  
**Protocol:**  
**IntelliPATH™ Automated Slides Staining System:**  
IPI061 is intended for use on the intelliPATH™ Automated Slides Stainer. Refer to the User Manual for specific instructions for use. When using the intelliPATH®, peroxide block with intelliPATH Peroxidase Blocking Reagent (IPBS5000) may be performed following heat retrieval.

**Technical Note:**  
This antibody, for intelliPATH and manual use, has been standardized with Biocare's MACH 4 detection system. Use TBS for washing steps.

**Limitations:**  
The optimum antibody dilution and protocols for a specific application can vary. These include, but are not limited to fixed, 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 titer levels 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. The clinical interpretation of any positive or negative staining should be evaluated within the context of clinical presentation, morphology and other histopathological criteria by a qualified pathologist. The clinical interpretation of any positive or negative staining should be complemented by morphological studies using proper positive and negative internal and external controls as well as other diagnostic tests.

**Quality Control:**  
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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/EE. 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]) (7)
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 in contact with sensitive areas, wash with copious amounts of water. (8)
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: