**SALL4**
Concentrated and Prediluted Monoclonal Antibody
901-384-111618

<table>
<thead>
<tr>
<th>Catalog Number:</th>
<th>CM 384 A, C</th>
<th>PM 384 AA</th>
<th>OAI 384 T60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description:</td>
<td>0.1, 1.0 mL, conc.</td>
<td>6.0 mL, RTU</td>
<td>60 tests, RTU</td>
</tr>
<tr>
<td>Dilution:</td>
<td>1:100</td>
<td>Ready-to-use</td>
<td>Ready-to-use</td>
</tr>
<tr>
<td>Diluent:</td>
<td>Renoir Red</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Intended Use:**
For In Vitro Diagnostic Use

**SALL4** [6E3] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of SALL4 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:**
SALL4, a zinc-finger transcriptional factor, is required for the maintenance of embryonic stem cell pluripotency by modulating Oct4, and is mapped to chromosome 20q13. SALL4 is a novel sensitive and specific marker for seminomas and ovarian primitive germ-cell tumors. Studies demonstrate that over 90% of tumor cells in intratubular germ-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.

**Protocol Recommendations (intelliPATH FLX and manual use):**

**Cont’d:**

**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™ Automated Slide Staining System):**

OAI384 is intended for use with the ONCORE. Refer to the User Manual for specific instructions for use. Protocol parameters in the Protocol Editor should be programmed as follows:

**Protocol Name:** SALL4

**Protocol Template (Description):** Ms HRP Template 1

**Dewaxing (DS Option):** DS Buffer

**Antigen Retrieval (AR Option):** AR1, high pH; 103°C

**Reagent Name, Time, Temp.:** SALL4, 30 min., 25°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 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:**

**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 in contact with sensitive areas, wash with copious amounts of water. (6)

3. Microbial contamination of reagents may result in an increase in nonspecific staining.
Precautions (Cont’d):
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: