SALL4
Concentrated and Prediluted Monoclonal Antibody
901-384-080917

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-cell neoplasias and embryonal carcinomas show strong SALL4 staining. In one study, 100 percent of all 31 yolk sac tumors (5 pediatric and 26 postpubertal) showed strong positive SALL4 staining of tumor cells, but were negative for Oct4. This marker is particularly useful in distinguishing yolk sac tumors from clear cell carcinomas. SALL4 is a promising new pan germ-cell marker and has been shown to be superior to PLAP and Oct4 antibodies.

Protocol Recommendations (manual use) Cont’d:
sections for 45-60 minutes. Allow solution to cool for 10 minutes then wash in distilled water.

Protocol Recommendations (ONCORE Automated Slide Staining System):
OAI384 is intended for use with the ONCORE Automated Slide Staining System. Refer to the ONCORE Automated Slide Staining System User Manual for specific instructions on its use. Protocol parameters in the ONCORE Automated Slide Stainer Protocol Editor should be programmed as follows:

Technical Note:
This antibody has been optimized for use with Biocare’s MACH 4 Universal HRP-Polymer Detection and ONCORE HRP Detection. Other Biocare polymer detection kits may be used; however, users must validate incubation times and protocols for their specific application. 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: 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. 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:

Catalog Number:  
CM 384 A, C  
PM 384 AA  
PM 384 T60

Description:  
0.1, 1.0 ml. concentrated  
6.0 ml, prediluted  
60 tests, prediluted

Dilution:  
1:100-1:200  
Ready-to-use  
Ready-to-use

Diluent:  
Senior Red  
N/A  
N/A

Protocol Recommendations (manual use)

Peroxidase Block: Block for 5 minutes with Biocare’s Peroxidized 1.
Pre-treatment Solution (recommended): Borg or Reveal
Pre-treatment Protocol:
Heat Retrieval Method:
Retrieve sections under pressure using Biocare’s Decloaking Chamber, followed by a wash in distilled water; alternatively, steam tissue
Precautions:
1. This antibody contains less than 0.1% sodium azide. Concentrations less than 0.1% are not reportable hazardous materials according to 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.
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 the data sheet provided. If atypical results occur, contact Biocare's Technical Support at 1-800-542-2002.