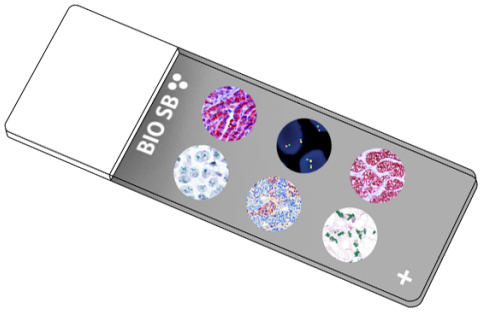
SALL4 Control Slides

CE IVD



Intended Use
For In Vitro Diagnostic Use.

Summary and Explanation
Spalt-like protein 4 is a transcription factor encoded by a member of the Spalt-like gene family, SALL4. There are four human SALL proteins (SALL1, 2, 3, and 4) with structural homology and playing diverse roles in embryonic development, kidney function, and cancer. SALL4 expression is low to undetectable in most adult tissues with the exception of germ cells and human blood progenitor cells. In normal testicular tissue, positive, weak SALL4 staining is observed in spermatogonia. In addition, a few (<5%) primary spermatocytes show dot-like weak SALL4 staining. Secondary spermatocytes, spermatids, spermatozoa, and Sertoli cells are negative for anti-SALL4. Leydig cells, rete testis, epididymis, spermatic cord fibroblasts, blood vessels, and hematopoietic cells are negative for SALL4.

SALL4 is reactivated and misregulated in various cancers, such as acute myeloid leukemia, B-cell acute lymphocytic leukemia, germ cell tumors, gastric cancer, breast cancer, hepatocellular carcinoma, lung cancer, and glioma. In many of these cancers, SALL4 expression has been compared in tumor cells to the normal tissue counterpart, e.g. it is expressed in nearly half of primary human endometrial cancer samples, but not in normal or hyperplastic endometrial tissue samples. Often, SALL4 expression is correlated with worse survival and poor prognosis such as in HCC, or with metastasis such as in endometrial cancer, colorectal carcinoma, and esophageal squamous cell carcinoma. It is unclear how SALL4 expression is deregulated in malignant cells, but DNA hypomethylation in its intron 1 region has been observed in B-ALL. In solid tumors such as germ cell tumors, SALL4 protein expression has become a standard diagnostic biomarker. SALL4 demonstrates 100% sensitivity and stains more than 90% tumor cells in all intratubular germ cell neoplasia, seminomas, dysgerminomas, embryonal carcinomas, and yolk sac tumor (both pediatric and postpubertal). SALL4 is also positive in most cases of teratoma and the mononucleated trophoblastic cells in choriocarcinomas. Most non-testicular tumors from various organs and sites are negative for SALL4, though an occasional carcinoma or sarcoma may show weak SALL4 staining in less than 25% of tumor cells.

Presentation
Five slides of SALL4 positive tissues, each mounted on Hydrophilic Plus Slides, provided in a plastic mailer.

Catalog No.	*Quantity*
BSB-9373-CS	5 slides
BSB 3189	5 slides
BSB 3196	5 slides

Storage Store at 20-25°C

Precautions
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information, refer to Safety Data Sheet for this product.
9. For complete recommendations for handling biological specimens, please refer to the CDC document, "Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories" (see References in this document).

Stability
This product is stable up to the expiration date on the product label.
Do not use after expiration date listed on package label.

IHC Protocol
1. Subject tissues to heat induced epitope retrieval (HIER) using a suitable retrieval solution such as ImmunoDNA Retriever with Citrate (BSB 0020-BSB 0023) or EDTA (BSB 0030-BSB 0033).
2. Any of three heating methods may be used:
a. TintoRetriever Pressure Cooker or Equivalent
Place tissues/slides in a staining dish or coplin jar containing the ImmunoDNA Retriever with Citrate or EDTA and place on trivet in the pressure cooker. Add 1-2 inches of distilled water to the pressure cooker and turn heat to high. Incubate for 15 minutes. Open and immediately transfer slides to room temperature.
b. TintoRetriever PT Module or Water Bath Method
Place tissues/slides in a pre-warmed staining dish or coplin jar containing the ImmunoDNA Retriever with Citrate or EDTA at 95°-99° C. Incubate for 30-60 minutes.
c. Conventional Steamer Method
Place tissues/slides in a pre-warmed staining dish or coplin jar containing the ImmunoDNA Retriever with Citrate or EDTA in a steamer, cover and steam for 30-60 minutes.
3. After heat treatment, transfer slides in ImmunoDNA Retriever with Citrate or EDTA to room temperature and let stand for 15-20 minutes.
4. For manual staining, perform antibody incubation at ambient temperature. For automated staining methods, perform antibody incubation according to instrument manufacturer's instructions.
5. Wash slides with ImmunoDNA washer or DI water.
6. Continue IHC staining protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical Protocol

Step	ImmunoDetector AP/HRP	PolyDetector AP/HRP	PolyDetector Plus HRP
Peroxidase/AP Blocker	5 min.	5 min.	5 min
Primary Antibody	30-60 min.	30-60 min.	30-60 min.
1st Step Detection	10 min.	30-45 min.	15 min.
2nd Step Detection	10 min.	Not Applicable	15 min.
Substrate- Chromogen	5-10 min.	5-10 min.	5-10 min.
Counterstain / Coverslip	Varies	Varies	Varies

Abbreviated IF Protocol

Step	Incubation Time
Rinse slides in IF wash buffer	5 minutes
Drain and wipe excess IF wash buffer off slide	
Conduct remaining steps in the dark	
Apply Antibody	30-60 minutes
Rinse with 3 changes of IF wash buffer	3x15 minutes each
Coverslip with IF mounting medium	

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

Product Limitations

Due to inherent variability present in immunohistochemical procedures (including fixation time of tissues, dilution factor of antibody, retrieval method utilized, and incubation time), optimal performance should be established through the use of positive and negative controls. Results should be interpreted by a qualified medical professional.

References

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8. Kobayashi D, et al. SALL4 is essential for cancer cell proliferation and is overexpressed at early clinical stages in breast cancer. International Journal of Oncology. 2011; 38 (4): 933–9.
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Symbol Key / Légende des symboles/Erläuterung der Symbole

EC REP QAdvis EAR AB Ideon Science Park Scheelevägen 17 SE-223 70 Lund, Sweden	Storage Temperature Limites de température Zulässiger Temperaturbereich	Manufacturer Fabricant Hersteller	REF Catalog Number Référence du catalogue Bestellnummer
IVD In Vitro Diagnostic Medical Device Dispositif médical de diagnostic in vitro In-Vitro-Diagnostikum	Read Instructions for Use Consulter les instructions d'utilisation Gebrauchsanweisung beachten	Expiration Date Utiliser jusque Verwendbar bis	LOT Lot Number Code du lot Chargenbezeichnung

Bio SB
BIOSCIENCE FOR THE WORLD
5385 Hollister Avenue, Bldg. 8, Ste. 108, Santa Barbara, CA 93111, USA
Tel. (805) 692-2768 | Tel. (800) 561-1145 | Fax. (805) 692-2769
E-mail: sales@biosb.com | Website: www.biosb.com