

## IVD DATA SHEET

### SALL4

Concentrated Rabbit Monoclonal Antibody

#### Intended Use:

For in Vitro Diagnostic Use

Epitomics' Rabbit Monoclonal Anti-Human SALL4, Clone EP299, is intended for use to qualitatively identify SALL4 by light microscopy in sections of formalin-fixed, paraffin-embedded tissue using immunohistochemical detection methodology. Interpretation of any positive or negative staining must be complemented with the evaluation of proper controls and must be made within the context of the patient's clinical history and other diagnostic tests. Evaluation must be performed by a qualified pathologist.

| Catalog number | Description                | Dilution    |
|----------------|----------------------------|-------------|
| AC-0298A       | 0.1 ml, concentrated       | 1:100-1:200 |
| AC-0298B       | 0.5 ml, concentrated       | 1:100-1:200 |
| AC-0298        | 1 ml, concentrated         | 1:100-1:200 |
| AC-0298BULK    | 2 ml or more, concentrated | 1:100-1:200 |

|                     |  |
|---------------------|--|
| <b>Immunogen:</b>   | A synthetic peptide corresponding to residues of human SALL4 protein |
| <b>Source:</b>      | Rabbit Monoclonal Antibody   |
| <b>Clone ID:</b>    | EP299  |
| <b>Isotype:</b>     | Rabbit IgG   |
| <b>Application:</b> | Immunohistochemistry for formalin-fixed paraffin-embedded tissue     |

#### Summary and Explanation:

The Sal-like protein 4, SALL4 is a zinc finger transcription factor located on chromosome 20q13.13-13.2. It is essential during development by maintaining embryonic stem cell pluripotency and self-renewal. Mutations in SALL4 lead to acro-renal-ocular and Okhiro syndromes, a disorder of the eyes and abnormalities of bones in the arms and hands.

Recently, SALL4 has been identified as a novel sensitive diagnostic marker for germ cell tumors. Strong SALL4 staining was observed in all seminoma/dysgerminoma/germinomas, embryonal carcinomas, and yolk sac tumors, yielding 100% sensitivity for these malignancies. Compared with  $\alpha$ -fetoprotein and glypican-3, SALL4 demonstrated superior sensitivity in detecting yolk sac tumors. Focal SALL4 staining was also observed in choriocarcinomas (66-71%) and teratomas (50-64%).

In non-germ cell tumors, SALL4 is expressed in all cases of acute myeloid leukemia, and majority of Precursor B-cell acute lymphoblastic lymphomas (79%). In a large immunohistochemical study of >3200 cases, SALL4 was also detected in ~20% of cases of ovarian, urothelial and gastric adenocarcinomas, and <5% in mammary, colorectal, prostatic and squamous cell carcinomas.

#### Reagent Provided:

Antibody to SALL4 is affinity purified and diluted in 10 mM phosphate buffered saline (PBS), pH 7.2 containing 1% bovine serum albumin (BSA) and 0.09% sodium azide (NaN<sub>3</sub>).

#### Storage and Stability:

Store at 2-8 °C. Don't use after expiration date provided on the vial. End user must validate any storage conditions other than those specified.

#### Procedures Recommended:

- 1. Pretreatment:** Epitope retrieval using Tris/EDTA (catalog #: SP-0004) with a pressure cooker.
- 2. Endogenous peroxidase block:** Block for 10 minutes at room temperature using peroxidase solution (catalog #: SP-0002).
- 3. Protein block:** Block for 10 minutes at room temperature using blocking solution (catalog #: SP-0003).
- 4. Primary antibody:** Incubate for 30 minutes.
- 5. Detection:** Follow instructions from the selected detection system (EpiPrecision™, a Biotin Streptavidin-HRP Detection, catalog #: DK-0001, 0003, or EpiVision™, a Rabbit Polymer Detection, catalog # DK-0002, 0004).

The antibody dilution and protocol may vary depending on the specimen preparation and specific application. Optimal conditions should be determined by the individual laboratory.

#### Performance Characteristics:

This antibody gives nuclear staining in positive cells. The recommended positive controls is yolk sac tumor for abnormal tissue.

#### Limitations:

Immunohistochemistry is a complex process. Variation in tissue selection, tissue processing, antigen retrieval, peroxidase activity, detection systems and improper counterstaining may cause variation in results.

#### References:

1. Cao D, et al.: *Cancer*. 2009, 115(12):2640-51.
2. Cui W, et al.: *Mod Pathol*. 2006, 19(12):1585-92.
3. Forghanifard MM, et al.: *J Biomed Sci*. 2013, 20:6.
4. Mei K, et al.: *Mod Pathol*. 2009, 22(12):1628-36.
5. Miettinen M, et al.: *Am J Surg Pathol*. 2014, 38(3):410-20.

101613 Rev. 00

