

IVD DATA SHEET

ROS1

Concentrated Rabbit Monoclonal Antibody

Intended Use:

For in Vitro Diagnostic Use

Epitomics' Rabbit Monoclonal Anti-Human ROS1, Clone EP282, is intended for use to qualitatively identify ROS1 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-0271EUA*	0.1 ml, concentrated	1:20
AC-0271EUB*	0.5 ml, concentrated	1:20
AC-0271EU	1 ml, concentrated	1:20
AC-0271EUBULK*	2 ml or more, concentrated	1:20

* Product not available in Canada

Immunogen:	A synthetic peptide corresponding to residues of human ROS1 protein
Source:	Rabbit Monoclonal Antibody
Clone ID:	EP282
Isotype:	Rabbit IgG
Application:	Immunohistochemistry for formalin-fixed paraffin-embedded tissue

Summary and Explanation:

ROS1 is a transmembrane protein with tyrosine kinase activity with putative function as a growth or differentiation factor receptor. ROS1 expression is limited in normal tissues to occasional staining cerebellum, stomach, small intestine, colon and kidney. Rearrangements of the *ROS1* proto-oncogene was originally detected in glioblastoma and cholangiocarcinoma. *ROS1* fusion partners include *CD74*, *SLC34A2* and *SDC4*, leading to oncogenic transformation.

ROS1 neoplastic transformation is widely studied in non-small cell lung cancer (NSCLC). While ROS1 is undetectable in the normal lung, studies have described *ROS1* rearrangements in 1-2% of NSCLC by FISH. Recent reports have demonstrated strong correlation between ROS1 immunoreactivity with FISH positivity.

Reagent Provided:

Antibody to ROS1 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 (NaN₃).

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 buffer (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 membrane and cytoplasm staining in positive cells. The recommended positive control is lung adenocarcinoma with *ROS1* rearrangement 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. Eom M, et al.: *Yonsei Med J.* 2013;54(3):650-7.
2. Hornick JL, et al.: *Mod Pathol.* 2015;28(5):732-9.
3. Rimkunas VM, et al.: *Clin Cancer Res.* 2012;18(16):4449-57.
4. Sholl LM, et al.: *Am J Surg Pathol.* 2013;37(9):1441-9.

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