EPITOMICS
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## IVD DATA SHEET

# ALK

Concentrated Rabbit Monoclonal Antibody

**Intended Use:**
For in Vitro Diagnostic Use

Epitomics' Rabbit Monoclonal Anti-Human ALK, Clone EP302, is intended for use to qualitatively identify ALK 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-0285A | 0.1 ml, concentrated | 1:100-1:200 |
| AC-0285B | 0.5 ml, concentrated | 1:100-1:200 |
| AC-0285 | 1 ml, concentrated | 1:100-1:200 |
| AC-0285BULK | 2 ml or more, concentrated | 1:100-1:200 |

**Immunogen:** A synthetic peptide corresponding to residues of human NPM-ALK fusion protein
**Source:** Rabbit Monoclonal Antibody
**Clone ID:** EP302
**Isotype:** Rabbit IgG
**Application:** Immunohistochemistry for formalin-fixed paraffin-embedded tissue

**Summary and Explanation:**
Anaplastic lymphoma kinase (ALK) is a receptor tyrosine kinase of the insulin receptor superfamily. ALK is typically expressed at low levels in regions of the developing central and peripheral nervous system.

ALK may be activated in cancer through multiple mechanisms. The most common mechanism is through formation of a fusion protein from chromosomal translocations, as in the case of anaplastic large cell lymphoma (ALCL) and inflammatory myofibroblastic tumors. ALK may also be amplified through mutation, as in neuroblastomas. Various solid tumors, such as non-small cell lung carcinoma (NSCLC) and brain cancers were also found to aberrantly express ALK.

ALK staining is present within both the nucleus and cytoplasm, and are positive in about 60% of ALCL. ALK protein expression by tumor cells is an independent prognostic factor that predicts a favorable outcome.

**Reagent Provided:**
Antibody to ALK 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 ($NaN_3$).

**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 Streptavitin-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 cytoplasm and nuclear staining in positive cells. The recommended positive control is ALK+ anaplastic large cell lymphoma 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:**
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