

Anti- human ALK Mouse Monoclonal Primary Antibody

Clone: 1A4

IVD

REF CE00001

CATALOG NUMBER

C0001MA01-MA 0.1 mL

C0001MA05-MA 0.5 mL

ENGLISH

Intended use

Anti- human ALK Mouse Monoclonal Primary Antibody is intended for the detection of anaplastic lymphoma kinase (ALK) protein expression in frozen or formalin fixed human tissues and cells. The clinical interpretation of any positive staining or its absence should be complemented by morphological and histological studies with proper controls. Evaluations should be made within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist. The antibody is intended for *in vitro* diagnostic (IVD) use.

Background

The ALK gene encodes a receptor tyrosine kinase, which belongs to the insulin receptor superfamily. This protein comprises an extracellular domain and hydrophobic stretch corresponding to a single pass transmembrane region, and an intracellular kinase domain. It plays an important role in the development of the brain and exerts its effects on specific neurons in the nervous system. This gene has been found to be rearranged, mutated, or amplified in a series of tumors including anaplastic large cell lymphomas, neuroblastoma, and non-small cell lung cancer. The chromosomal rearrangements are the most common genetic alterations in this gene, which result in creation of multiple fusion genes in tumorigenesis, including ALK (chromosome 2)/EML4 (chromosome 2), ALK/RANBP2 (chromosome 2), ALK/ATIC (chromosome 2), ALK/TFG (chromosome 3), ALK/NPM1 (chromosome 5), ALK/SQSTM1 (chromosome 5), ALK/KIF5B (chromosome 10), ALK/CLTC (chromosome 17), ALK/TPM4 (chromosome 19), and ALK/MSN (chromosome X).[Provided by RefSeq, Jan 2011].

Alternative names: Anaplastic lymphoma kinase also known as ALK tyrosine kinase receptor or CD246

Reagent provided

Anti- human ALK Mouse Monoclonal Primary Antibody (Clone: 1A4) is provided in liquid form in 20mM Sodium phosphate, 150mM Sodium chloride, 0.09% Sodium azide, pH 7.4. The isotype of the antibody is IgG2b. The total protein concentration is 0.5mg/mL.

For Immunohistochemistry the primary antibody may be used at a working dilution of 1:100 – 1:200 for formalin-fixed, paraffin-embedded human tissues, and this can be dependent upon the detection system used. These are guidelines only, and the optimal dilutions should be determined by the individual laboratory.

Immunogen

Human recombinant protein fragment corresponding to amino acids 1300-1620 of human ALK (NP_004295) produced in E.coli.

Specificity

The specificity of the anti- human ALK Mouse Monoclonal Primary Antibody was established on known ALK positive and negative non-small cell carcinoma (NSCLC). The anti-ALK presented no staining on formalin fixed ALK negative NSCLC tissue and positive staining on formalin fixed ALK positive NSCLC tissue using immunohistochemical (IHC) test methods.

Materials Required but Not Supplied

Antibody diluent, HIER solution, Antibody detection kits, Chromogen, Staining reagents, negative and positive tissue control slides are not included.

Precautions

1. For use by trained professionals only.
2. This product contains sodium azide (NaN_3), a chemical highly toxic in pure form. At product concentrations, though not classified as hazardous, NaN_3 may react with lead and copper plumbing to form highly explosive build-ups of metal azides. Upon disposal, flush with large volumes of water to prevent metal azide build-up in plumbing.
3. Wear appropriate Personal Protective Equipment to avoid contact with eyes and skin.
4. Unused reagents should be disposed of according to local, State, and Federal regulations.

Storage

Store at 2-8°C. Do not use the product past the expiration date indicated on the label. If reagents are stored under any other conditions, the end user must verify the acceptability of those conditions. There are no obvious signs to indicate instability of this product therefore, positive and negative controls should be run simultaneously with patient specimens.

Specimen Preparation

Paraffin Sections

Anti- human ALK Mouse Monoclonal Primary Antibody can be used on formalin-fixed, paraffin-embedded tissue sections at a working dilution of 1:100 to 1:200. Anti- human ALK Mouse Monoclonal Primary Antibody working dilution requires 20 minutes of pretreatment with Heat Induced Epitope Retrieval (HIER) for staining. We recommend using HIER TEE Buffer pH9.0, which showed optimal staining at a dilution of 1:200 on ALK positive Non-Small Cell Lung Carcinoma and negative staining on ALK negative Non-Small Cell Lung Carcinoma and normal lung tissue using two-step detection systems (Polink-2 Broad HRP).

Staining procedure

Manual Staining Procedure

1. Deparaffinize slides.
2. Submerge slides in peroxidase quenching solution for ~10 minutes and rinse with PBS-T 3 times, 2 minutes each.
3. Heat Induced Epitope Retrieval is required for this antibody.
4. Apply serum blocking solution.[Optional]
5. Apply primary antibody and incubate for 30-60 minutes at room temperature. After incubation wash with PBS-T 3 times, 2 minutes each.
6. Apply secondary antibody and incubate according to the data sheet of the detection system. Wash with PBS-T 3 times, 2 minutes each.
7. Apply enzyme conjugate and incubate according to data sheet of detection system. Wash with PBS-T 3 times, 2 minutes each.
8. Apply chromogen and incubate 5-10 minutes and rinse with distilled water.

Staining interpretation

The cellular staining pattern for Anti- human ALK Mouse Monoclonal Primary Antibody can be cytoplasmic or nuclear or both dependent upon the tumor type.

Performance Characteristics

Predicted Staining in Normal Tissue/Cells

Normal human lung, skin, and pancreas were shown to be negative for this antibody. Non-small cell lung carcinoma with no ALK mutation was shown to be negative with this antibody.

Predictive Staining in Tumor

Anti- human ALK Mouse Monoclonal clone 1A4 produced strong nuclear and cytoplasmic positive stain when screened on anaplastic large cell lymphoma. In non-small cell lung carcinoma containing an ALK mutation produced positive cytoplasmic staining with this antibody. In a mouse xenograft generated from a cell line overexpressing mutated ALK protein, this antibody produced strong cytoplasmic staining.

References

1. UK NEQAS ICC & ISH Immunocytochemistry Journal. Run 108 (January 2015)
2. Gruber, K., et al., A Novel, Highly Sensitive ALK Antibody 1A4 Facilitates Effective Screening for ALK Rearrangements in Lung Adenocarcinomas by Standard Immunohistochemistry. J Thorac Oncol. 2015 Apr;10(4):713-6.

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