GENE BIO SOLUTION

ALK (5A4)

Format	Catalog No.	Pack size	Dilution
Concentrated	GB3041A,B	0.1, 0.5 mL	1:100
Prediluted	GB3041AA	6.0 mL	Ready to use

PRODUCT DESCRIPTION -

ALK Antibody (p80) identifies the formalin-resistant epitope of the native anaplastic lymphoma kinase (ALK) protein. ALK antibody specifically identifies t(2;5)-positive cells, resulting in pronounced cytoplasmic staining accompanied by nuclear staining. Anaplastic large cell lymphoma (ALCL) is a diverse collection of diseases characterized by morphology, immunophenotyping, and clinical presentation, which can complicate diagnosis due to its resemblance to Hodgkin's lymphoma. Studies indicate that ALK mostly stains CD30+ ALCL. It has been demonstrated to not stain Hodgkin's disease (Reed-Sternberg cells). ALK may be utilized in conjunction with CD15, CD30, TIA-1, and EMA in a panel.

INTENDED USE -

ALK [5A4] is a mouse monoclonal antibody designed for laboratory applications to qualitatively identify ALK protein or ALK-NPM chimeric protein using immunohistochemistry (IHC) in formalin-fixed paraffin-embedded (FFPE) human tissues. The clinical interpretation of any staining or its absence must be supplemented by morphological studies utilizing appropriate controls and assessed in conjunction with the patient's clinical history and other diagnostic tests by a skilled pathologist.

SUMMARY AND EXPLANATION -

Anaplastic large cell lymphoma (ALCL) is linked to a t(2;5) chromosomal translocation, which leads to the fusion of the ALK (anaplastic lymphoma kinase) gene with the NPM (nucleophosmin) gene. The gene fusion results in the creation of the chimeric NPM-ALK protein, which is thought to contribute to lymphomagenesis. The ALK [5A4] monoclonal antibody identifies the normal ALK protein, in addition to the NPM-ALK and EML4-ALK fusions, which are prevalent in non-small cell lung cancer (NSCLC), along with all other recognized pathogenic ALK fusions. ALK-targeting tyrosine kinase inhibitors (TKIs) have demonstrated significant efficacy as treatments in patients with ALK-rearranged non-small cell lung cancer (NSCLC). Assessing eligibility for ALK TKI therapy necessitates prompt and precise screening to identify ALK rearrangement, achievable through the detection of ALK fusion protein overexpression via immunohistochemistry (IHC) or ALK gene rearrangement

through in situ hybridization (ISH). Research comparing fluorescence in situ hybridization (FISH), chromogenic in situ hybridization (CISH), and immunohistochemistry (IHC) demonstrated concordance. According to our findings, immunohistochemistry utilizing the ALK [5A4] antibody may serve as an effective screening technique to identify NSCLC patients with ALK.

PRINCIPLE OF PROCEDURE -

Antigen detection in tissues and cells involves a multi-step immunohistochemistry process. The first step attaches the primary antibody to its designated epitope. Following the tagging of the antigen with a primary antibody, a one-, two-, or three-step detection protocol may be utilized. The one-step approach will utilize an enzyme-conjugated polymer that attaches to the main antibody. A two-step protocol will involve the addition of a secondary antibody to bind to the original antibody. An enzyme-conjugated polymer is subsequently introduced to bind to the secondary antibody. The three-step detection protocol will incorporate a secondary antibody to bind to the primary antibody, succeeded by a linker antibody step to enhance binding efficacy. An enzyme-conjugated polymer is subsequently introduced to attach to the linkerantibody.Thepresenceofboundantibodiesisdemonstratedbyacolorimetric response.

SOURCE - Mouse monoclonal

SPECIES REACTIVITY - Human; others not tested

CLONE - 5A4

ISOTYPE - : IgG1

PROTEIN CONCENTRATION - Call for lot specific Ig concentration.

EPITOPE/ANTIGEN - aa 419-520 of NPM-ALK transcript

CELLULAR LOCALISATION - Cytoplasmic and nuclear staining (dot-like)

POSITIVE TISSUE CONTROL - Anaplastic large cell lymphoma

KNOWN APPLICATIONS - I mmunohistochemistry
30-40 min. At RT. Staining of formalin-fixed tissues requires heating tissue sections in between pH 7.4 - 9.0 for 45 min at 95ºC followed by cooling at room temperature for 20 minutes.

SUPPLIED AS - Buffer with protein carrier and preservative

STORAGE AND STABILITY -

Store at 2°C to 8°C. The product is stable to the expiration date printed on the label, when stored under these conditions. Do not use after expiration date. Diluted reagents should be used promptly; any remaining reagent should be stored at 2°C to 8°C.

Materials required but not provided -

1) Positivetissuecontrol-Anaplasticlargecelllymphoma
2) Negativecontroltissue(internalorexternal)
3) Microscopeslidesandcoverslips
4) Stainingjarsorbaths
5) Timer
6) Xyleneorxylenesubstitute
7) Ethanolorreagentalcohol
8) Deionizedordistilledwater
9) Heatingequipmentorenzymefortissuepretreatmentstep
10) Detection system
11) Chromogen
12) Wash buffer
13) Hematoxylin
14) Antibody diluents
15) Peroxide block
16) Light microscope
17) Mounting medium

LIMITATIONS-

The optimum antibody dilution and protocols for a specific application can vary. These include, but are not limited to fixation, heat-retrieval method, incubation times, tissue section thickness and detection kit used. Due to the superior sensitivity of these unique reagents, the recommended incubation times and titers listed are not applicable to other detection systems, as results may vary. The data sheet recommendations and protocols are based on exclusive use of Genebio products. Ultimately, it is the responsibility of the investigator to determine optimal conditions.