ALK [5A4]

Concentrated and Prediluted Monoclonal Antibody
902-3041-072717

BIOCARE MEDICAL

Catalog Number:	**ACR 3041 A, B**	**APR 3041 AA**
Description:	0.1, 0.5 ml, concentrated	6.0 ml, prediluted
Dilution:	1:50-1:100	Ready-to-use
Diluent:	Renoir Red	N/A

Intended Use:
For Research Use Only. Not for use in diagnostic procedures.

Summary and Explanation:
ALK (p80) recognizes the formalin-resistant epitope of native anaplastic lymphoma kinase (ALK) protein. ALK recognizes a 200 kDa transmembrane molecule expressed only in neural tissues. The ALK reacts with normal ALK protein, as well as with the chimeric protein ALK-NPM. ALK specifically labels t(2;5)-positive cells giving strong cytoplasmic staining that is also associated with nuclear staining. Anaplastic large cell lymphoma (ALCL) is a heterogeneous group of diseases by morphology, immunophenotyping and clinical presentation. It can be difficult to diagnose because of its similarity to Hodgkin's lymphoma. However, treatment and prognosis of Hodgkin's and ALCL is very different, and it is imperative to diagnose correctly. Research has also shown that a subset of lung adenocarcinomas harbor rearrangements of the ALK gene that results in the pathologic expression of a fusion protein, most commonly EMLA-ALK. Patients with ALK-rearranged lung adenocarcinomas are unresponsive to tyrosine kinase inhibitors that target EGFR, but have shown dramatic improvement in response to tyrosine kinase inhibitors that target ALK in ongoing clinical trials. The results from studies comparing FISH, CISH and IHC were concordant. The sensitivity and specificity of IHC was reported as 100% and 95% respectively. Based on these findings, the IHC assay using the 5A4 antibody reliably detected non-small cell lung cancer with ALK rearrangement and may be useful as a screening method to identify these tumors. Research has shown that ALK stains the majority of CD30+ ALCL. It has not been shown to stain Hodgkin's disease (Reed-Sternberg cells). ALK should beused in a panel with CD15, CD30, TIA-1 and EMA.

Principle of Procedure:
Antigen detection in tissues and cells is a multi-step immunohistochemical process. The initial step binds the primary antibody to its specific epitope. After labeling the antigen with a primary antibody, a secondary antibody is added to bind to the primary antibody. An enzyme label is then added to bind to the secondary antibody; this detection of the bound antibody is evidenced by a colorimetric reaction.**Source:** Mouse monoclonal

Species Reactivity: Human; others not tested
Clone: 5A4
Isotype: IgG1
Total Protein Concentration: ~10 mg/ml. Call for lot specific Ig concentration.
Epitope/Antigen: aa 419-520 of NPM-ALK transcript
Cellular Localization: Cytoplasmic and nuclear staining (dot-like)
Positive Control: Anaplastic large cell lymphoma
Known Applications:
Immunohistochemistry (formalin-fixed paraffin-embedded tissues)
Supplied As: Buffer with protein carrier and preservative
Storage and Stability:
Store at 2ºC to 8ºC. Do not use after expiration date printed on vial. If reagents are stored under conditions other than those specified in the package insert, they must be verified by the user. Diluted reagents should be used promptly; any remaining reagent should be stored at 2ºC to 8ºC.

Staining Protocol Recommendations:
Peroxide Block: Block for 5 minutes with Biocare's Peroxidazed 1.
Pretreatment: Perform heat retrieval using Biocare's Diva Decloaker. Refer to the Diva Decloaker product data sheet for specific instructions.
Protein Block (Optional): Incubate for 5-10 minutes at RT with Biocare's Background Punisher.
Primary Antibody: Incubate for 30 minutes at RT.
Probe: Incubate for 10 minutes at RT with a secondary probe.
Polymer: Incubate for 10 minutes at RT with a tertiary polymer.
Chromogen:
Incubate for 5 minutes at RT with Biocare's DAB – OR – Incubate for 5-7 minutes at RT with Biocare's Warp Red.
Counterstain:
Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.
Limitations:
This product is provided for Research Use Only (RUO) and is not for use in diagnostic procedures. Suitability for specific applications may vary and it is the responsibility of the end user to determine the appropriate application for its use.
Precautions:
1. This antibody contains less than 0.1% sodium azide. Concentrations less than 0.1% are not reportable hazardous materials according to U.S. 29 CFR 1910.1200, OSHA Hazard communication and EC Directive 91/155/EC. Sodium azide (NaN_3) used as a preservative is toxic if ingested. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. Upon disposal, flush with large volumes of water to prevent azide build-up in plumbing. (Center for Disease Control, 1976, National Institute of Occupational Safety and Health, 1976) (5)
2. Specimens, before and after fixation, and all materials exposed to them should be handled as if capable of transmitting infection and disposed of with proper precautions. Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents and specimens. If reagents or specimens come in contact with sensitive areas, wash with copious amounts of water. (6)
3. Microbial contamination of reagents may result in an increase in nonspecific staining.
4. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change.
5. Do not use reagent after the expiration date printed on the vial.
6. The SDS is available upon request and is located at http://biocare.net/.
Technical Support:
Contact Biocare's Technical Support at 1-800-542-2002 for questions regarding this product.
References:
1. Falini B, *et al.* ALK expression defines a distinct group of T/Null lymphomas ("ALK lym homas") with a wide morphological spectrum. Am J Pathol. 1998 Sep; 153(3):875-86.
2. Mino-Kenudson M, *et al.* A novel highly sensitive antibody allows for the routine detection of ALK-rearranged lung adenocarcinomas by standard immunohistochemistry. Clin Cancer Res. 2010 Mar 1; 16(5):1561-71.

Biocare Medical
60 Berry Drive
Pacheco, CA 94553
USA

Tel: 800-799-9499 | www.biocare.net | Fax: 925-603-8080

References Cont'd:
3. Paik JH, *et al.* Screening of anaplastic lymphoma kinase rearrangement by immunohistochemistry in non-small cell lung cancer: correlation with fluorescence in situ hybridization. J Thorac Oncol. 2011 Mar; 6(3):466-72.
4. Kim H, *et al.* Detection of ALK gene rearrangement in non-small cell lung cancer: a comparison of fluorescence in situ hybridization and chromogenic in situ hybridization with correlation of ALK protein expression. J Thorac Oncol. 2011 Aug; 6(8):1359-66.
5. McLeer-Florin A, *et al.* Dual IHC and FISH testing for ALK gene rearrangement in lung adenocarcinomas in a routine practice: a French study. J Thorac Oncol. 2012 Feb; 7(2):348-54.

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