CE IVD

Mouse anti-ALK (p80)

Cat. No.: AIB-30309 (0.5 ml Concentrate);

Instructions for use

Intended use
This antibody is designed for the specific localisation of anaplastic lymphoma kinase (ALK) protein in formalin-fixed, paraffin-embedded tissue sections. Anti-ALK (p80) antibody is intended for in vitro diagnostic use.

Specifications

Specificity:	ALK protein
Clone:	5A4
Isotype:	Mouse IgG1
Species reactivity:	Human +, others not tested
Immunogen:	AA419-520

Summary and Description
ALK (p80) antibody binds to a 200 kDa transmembrane molecule expressed only in neural tissues. This protein is known as anaplastic lymphoma kinase (ALK) and the antibody detects the formalin-resistant epitope of native ALK. The ALK antibody reacts with normal ALK protein, as well as with the chimeric protein ALK-NPM.
Anti-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 harbour 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 nonsmall cell lung cancer with ALK rearrangement and may be useful as a screening method to identify these tumours.
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 be used in a panel with CD15, CD30, TIA-1 and EMA.

Reagent provided
Mouse monoclonal antibody in buffer with carrier protein and preservative for stabilisation in the following format:
Concentrate: 0.5 ml (Cat. No. AIB-30309)

Dilution of primary antibody
Dilution of Nordics Biosite's Systems' concentrated antibody depends on the detection system used. The final working dilution must always be determined by the user. The elaboration of staining protocol should be done by an experienced specialist. For Nordic Biosite's Systems' recommendations see chapter 'Staining procedure'.

Explanations of the symbols on the product label:

REF	Catalog Number Bestellnummer Reference du catalogue	LOT	Batch Code Chargenbezeichnung Code du lot	Manufacturer Nordic BioSite AB Propellervägen 4A S-183 62 Täby Sweden Tel: +46 (0)8 5444 33 40 Fax: +46 (0)8 756 94 90 info@nordicbiosite.com www.nordicbiosite.com
	Use By Verwendbar bis Utiliser jusque	IVD	In Vitro Diagnostic Medical Device In vitro Diagnostikum Dispositif médical de diagnostic in vitro	
	Consult Instructions for use Gebrauchsanweisung beachten Consulter les instructions d'utilisation		Temperature Limitation Lagerungstemperatur Limites de température	

Storage and handling
The antibody should be stored at 2-8°C without furt her dilution.
Dilutions of the concentrated antibody should be done in a suitable antibody dilution buffer. The diluted antibody should be stored at 2-8°C after use. Stability of t his working solution depends on various parameters and has to be confirmed by appropriate controls. The antibody provided is suitable for use until the expiry date indicated on the label, if stored at 2-8°C. Do not use product after the expiry date. Positive and negative controls should be run simultaneously with all specimens. If unexpected staining is observed which cannot be explained by variations in laboratory procedures and a problem with the antibody is suspected, contact Nordic Bisoite's Systems' technical support or your local distributor.

Precautions
Use through qualified personnel only.
Wear protective clothing to avoid contact of reagents and specimens with eye, skin and mucous membranes. If reagents or specimens come in contact with sensitive area, wash with large amounts of water.
Microbial contamination of the reagent must be avoided, since otherwise non-specific staining may occur.
Sodium azide (NaN3), used for stabilisation, is not considered hazardous material in the concentration used. Reaction of sodium azide with lead or copper in drainage pipes can result in the formation of highly explosive metallic azides. Sodium azide should be discarded in a large volume of running water to avoid formation of deposits. Material safety data sheets (MSDS) are available upon request. Staining procedure for formalin-fixed paraffin sections Refer to the following table for conditions specifically recommended for this antibody. Also refer to detection system data sheets for guidance on specific staining protocols or other requirements.

Parameters	Nordic BioSites recommendations
*Pre-treatment	Heat Induced Epitope Retrieval(for example in Citrate pH6.0 pH 6.0 (BCB-20015/-20016)
*Control tissue	Anaplastic large cell Lymphoma
*Working dilution	1:100-1:200 (for concentrates)
*Incubation time	30-60 minutes

Quality control
The recommended positive control tissue for this antibody is an anaplastic large cell lymphoma. We recommend carrying out a positive and a negative control with every staining run. Please refer to the instructions of the detection system for guidance on general quality control procedures.

Troubleshooting
If you observe unusual staining or other deviations from the expected results please read these instructions carefully, refer to the instructions of the detection system for relevant information or contact your local distributor.

Expected results
This antibody stains positive in nuclei and cytoplasm in formalin-fixed, paraffin-embedded tissue sections of anaplastic large cell lymphoma. The staining pattern is dot-like. Further details about the expression pattern of ALK (p80) can be found in the chapter 'Summary and Description'. Interpretation of the staining results is solely the responsibility of the user. Any experimental result should be confirmed by a medically established diagnostic procedure.

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Limitations of the Procedure
Immunohistochemistry is a complex technique involving both histological and immunological detection methods. Tissue processing and handling prior to immunostaining, for example variations in fixation and embedding or the inherent nature of the tissue can cause inconsistent results (Nadji and Morales, 1983). Endogenous peroxidase, alkaline phosphatase or biotin may cause non-specific staining depending on the detection system used. Tissues containing Hepatitis B Surface Antigen (HBsAg) may give false positive results with HRP (horse radish peroxidase) detection systems (Omata et al, 1980). Inadequate counterstaining and mounting can influence the interpretation of the results. Nordic Biosite's Systems warrants that the product will meet all requirements described from its shipping date until the expiry date is reached, if the product is stored and utilised as recommended. No additional guarantees can be given. Under no circumstances shall Nordic Biosite's System be liable for any damages arising out of the use of the reagent provided.

Performance characteristics
Nordic Bisoite's Systems has conducted studies to evaluate the performance of the antibody for use with a standard detection system. The product has been found to be sensitive and specific to the antigen of interest with minimal or no cross-reactivity.

Bibliography

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Falini B et al. Am J Pathol 153:875-886, 1998
Nadji M and Morales AR Ann N.Y. Acad Sci 420:134-9, 1983 Omata M et al. Am J Clin Pathol 73(5): 626-32, 1980

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